

12. Medical Information:

Within the past 10 years has any proposed insured ever been hospitalized, been a patient at the hospital, or been under treatment, medical or dental or special treatment of any of the following:

a. The brain or nervous system, including but not limited to: dizziness, fainting, convulsions, paralysis, stroke, mental or nervous disorder?.....

b. The respiratory system, including but not limited to: shortness of breath, persistent hoarseness or cough, bronchitis, asthma, emphysema, tuberculosis, or chronic respiratory disorder?.....

c. The heart or blood vessels, including but not limited to: chest pain, high blood pressure, rheumatic fever, heart murmur, heart attack, varicose veins, or other disorder of the heart or blood vessels?.....

d. The gastro-intestinal tract, liver or pancreas, including but not limited to: jaundice, intestinal bleeding, ulcer colitis, recurrent indigestion, or other disorder of the stomach, intestines, liver or gall bladder?.....

e. The genito-urinary organs, including but not limited to: venereal diseases, sugar, albumin, blood or pus in urine; stone or other disorder of kidney, urinary bladder, or prostate?.....

f. The eyes, ears, nose or throat?.....

g. Diabetes, thyroid or other glandular disorders, including but not limited to thyroid glands?.....

h. Arthritis, sprains, gout, soreness of the muscles, bones, including but not limited to spine, back or joints?.....

i. Electrocution or burns?.....

j. Cyst, tumor, cancer, or growth of any kind?.....

k. Acquired Immune Deficiency Syndrome (AIDS), AIDS related complex (ARC), or AIDS related condition?.....

l. Allergies, anemia or other disorders of the blood?.....

m. The reproductive organs, breasts, menstruation or complications of pregnancy?.....

n. Alcoholism, chemical dependency or drug addiction?.....

13. Within the past 5 years, has any proposed insured been advised to have a surgical operation, enter a hospital or other institution or been under observation or taking treatment not stated above?.....

Details to Questions 10-13 Give Complete details of any "Yes" answer, including dates and results of treatment, name and complete address of doctor and hospital (attach additional sheet if necessary).

Person No. & Question No.

14. What is the name and address of personal physician(s)?

Person No.	Date and Purpose of Last Visit	Result	Physician's name, address and phone number

I authorize any physician, medical practitioner, hospital, clinic, other medical care facility, insurance or reinsuring company, the Medical Information Bureau, Inc., consumer reporting agency, or employer, having information available as to employment, other insurance, medical care, advice, treatment and prognosis with respect to any physical or mental condition regarding me or my minor children to be insured, to give the information to _____, its reinsurer or any agency acting on _____'s behalf.

I understand the information will be used by _____ to determine eligibility for insurance. I know I will receive a copy of this authorization upon request. I understand that this authorization is valid for two and _____ years from the date signed and that a photocopy will be valid as the original.

I certify I have accurately recorded herein the information supplied by the applicant and that an Outline of Coverage for the policy applied for has been given the applicant. Replacement of other insurance [] is [] is not involved in this transaction.

X _____
Primary Agent Signature

PRINT-Primary Agent Name Agent No. Office No.

X _____
Second Agent Signature

PRINT-Second Agent Name Agent No. Office No.

Summary

_____ to be interviewed if an investigative consumer report is needed in connection with this application.

I acknowledge receiving the RECEIPT and NOTICE. I have read and understood the information on both sides of this receipt including the language regarding the effective date of the policy, if issued.

I understand that the agent does not have the right to waive the answer to any question in this application, to pass on insurability, to waive any of the Company's rights or requirements, or to make or alter any contract.

I have carefully read the above application together with my answers and represent that they are complete and true.

I acknowledge receiving an Outline of Coverage.

Signed at _____ Date _____
City & State

X _____
Proposed Insured's Signature

X _____
Spouse's Signature

Mail Policy to [] Agent [] Proposed Insured

Agent Business Phone Number (_____) _____

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The Technology Assessment Board approves the release of this report. The views expressed in this report are not necessarily those of the Board, OTA Advisory Council, or individual members thereof.

MEDICAL TESTING

and Health Insurance

Summary

CONGRESS OF THE UNITED STATES OFFICE OF TECHNOLOGY ASSESSMENT

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Foreword

Tests to identify individuals who are likely to develop serious diseases are being rapidly developed. Some of these tests are directed at diseases for which there are presently no known therapies, thereby raising questions over the social consequences of identifying susceptible persons. Other tests are directed at diseases that are among the foremost causes of morbidity and mortality, such as cardiovascular diseases and cancer, but for which clear-cut relationships between test positivity and a high probability of developing disease have yet to be established. Available tests for identifying persons infected with the AIDS virus are very accurate, but whom to test is a highly controversial issue because of the social consequences of being identified as a carrier of the AIDS virus.

The health status and risk of developing disease of individuals applying for health insurance are routinely evaluated by private health insurers, and applicants may be declined altogether, charged higher premiums, or have certain illnesses excluded from coverage. Medical testing may be included in evaluating the applicant, so wider use of diagnostic and predictive medical tests by insurers is a real possibility as such tests are improved and more tests become available. Many employers—especially large employers—are also foregoing the use of traditional insurers and are self-insuring the health care costs of their employees, so they may have similar incentives to use medical tests when hiring prospective employees.

Such uses of medical tests may lead to substantial costs to government if private insurance becomes too costly or unavailable to selected individuals. Furthermore, approximately 15 percent of the population of the United States do not have health insurance, and an additional 8 to 26 percent of the population under age 65 are underinsured. Thus, use of medical tests in determining insurability and employability not only affects the balance between governmental and private sector financing of health care, but also can aggravate the problem of the uninsured and underinsured.

This assessment examines existing and developing medical tests and their current and potential uses by health insurers and employers. Two related reports have previously been issued as part of this study. *AIDS and Health Insurance: An OTA Survey* was issued in February 1988 and examined health insurance underwriting practices and AIDS claims experience for individually underwritten insurance policies. *The Impact of AIDS on the Kaiser Permanente Medical Care Program (Northern California Region)* was released in July 1988.

OTA was ably assisted in this study by an advisory panel, chaired by Irving Lewis, Emeritus Professor of Public Policy and Community Health at the Albert Einstein College of Medicine. Many individuals and organizations with expertise and interest in these areas also provided information and reviewed a draft of the report. The final responsibility for the content of this assessment rests with OTA. Key staff involved in the analysis and writing were Larry Miike, Jill Eden, Maria Hewitt, Laurie Mount, and Ellen Smith.


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NOTE: OTA gratefully acknowledges the members of this advisory panel for their valuable assistance and thoughtful advice. The panel does not, however, necessarily approve, disapprove, or endorse this report. OTA assumes full responsibility for the report and the accuracy of its contents.

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Summary and Conclusions

INTRODUCTION

For the great majority of Americans, access to health care, and the health insurance that makes such access possible, is provided through the private sector. Medicare and Medicaid have played an indispensable role in making health care available to the indigent and near indigent, and to the elderly and some handicapped persons.¹ Yet there are approximately 31 million to 37 million people, or from 13.3 to 15.7 percent of the estimated 236 million persons living in the United States in 1986, who have no health insurance (table 1-1). An additional 8 to 26 percent of persons under age 65 have inadequate health insurance. (The estimates depend on the definition of "inadequate health insurance" that is used—see app. A in the full report.)

Persons who apply for health insurance on their own, instead of through group policies such as employment-based plans, usually have their health status evaluated by health insurers to determine whether or not they are in fact insurable. (This evaluation is commonly referred to as "underwriting.") For insurable applicants, some might be determined to be at such an added health risk to require higher than standard premium rates and/or insurance policies that exclude from coverage specified diseases or conditions that the applicant already has or is at significant risk of developing. Those with significant disease or risk of disease may be denied insurance altogether.

When underwriting individual applicants for health insurance, insurers rely at a minimum on a medical history questionnaire, and less frequently on such other sources of information as a statement from the applicant's attending physician or actual records from the physician, medical tests, and physical exams.

Advances in predictive and diagnostic medical testing are increasing our capability to identify individuals who are likely to develop serious dis-

Table 1-1.—Percent Distribution and Number of Persons by Insurance Coverage Status, United States, 1986

Age	Coverage status		
	All ^a	Covered ^b	Not covered ^c
Percent distribution			
All ages	100.0	86.7	13.3
Under 18 years	100.0	85.4	14.6
18-24 years	100.0	75.3	24.7
25-44 years	100.0	85.2	14.8
45-64 years	100.0	90.0	10.0
65 years and over	100.0	99.3	0.7
Number in thousands			
All ages	236,348	201,830	31,010
Under 18 years	63,132	52,862	9,071
18-24 years	26,721	19,751	6,466
25-44 years	74,260	62,382	10,853
45-64 years	44,698	39,708	4,418
65 years and over	27,538	27,126	202

^aPercent distribution excludes unknown coverage status; frequency includes unknown coverage status.

^bCovered by private health insurance, Medicare, public assistance, or military. Veterans Administration health benefits.

^cNot covered under any of the four health-care plans. Estimates range from 13.3 to 15.7 percent, or 31.0 to 37.2 million persons (see also app. A of the full report).

SOURCE: P. Ries, "Health Care Coverage by Age, Sex, Race, and Family Income: United States, 1986," NCHS *advancedata*, No. 139, Sept. 18, 1987.

eases. The use of these tests by health insurers may (or may not) make private health insurance unavailable or too costly even to a number of presently insured persons and their dependents if analyses of their risks improve. Already, tests to detect the presence of antibodies to the AIDS virus (HIV, for "human immunodeficiency virus") have brought the issue of private health insurance availability to the forefront of public policy discussions on health insurance for persons infected with HIV.

People with individually obtained health insurance comprise only 10 to 15 percent of all persons with health insurance. Furthermore, group applicants for health insurance, who comprise 85 to 90 percent of all persons with health insurance and who obtain their health insurance predominantly through their workplace, seldom if ever are subjected to individual determinations of their health status. Premiums for group health insurance policies are usually "experience-rated," which is based principally on the actual health care costs most recently incurred by the group.

¹In addition, the medical care systems of the Department of Defense and the Veterans Administration provide medical care to active and retired military persons, and to military veterans.

However, even persons presently insured through group health insurance are not exempt from the possibility of unavailable or unaffordable health insurance. Containment of ever-increasing health care costs is a high priority for employers, who also might be interested in using predictive medical tests to screen out prospective employees who might consume a disproportionate share of funds allocated to meet employee health care expenses. The increasing propensity of employers, especially large employers, to self-insure their employees' health care expenses is a reflection of the business community's concern over rising health care costs. Furthermore, although self-insured plans are subject to Internal Revenue Service and Department of Labor review and regulations, current law makes these self-insured health care plans free of State insurance department review and regulations, leading to fewer restraints on self-insured plans than on traditional health insurance plans for employers who might decide to use medical testing to decrease their employee health care expenses.

Such potential actions by the private sector have obvious consequences on public sector spending for health care. To what extent are such actions already occurring, what is the potential for their occurring, and what are the potential consequences if these actions are adopted on a wide scale by private insurers and the business community? Are the current availability of the AIDS antibody test, its ability to identify those

infected with the AIDS virus, and the growing percent of infected persons who progress on to frank disease, forewarnings of these private-public sector issues? Will the way in which we address the financing of AIDS patients be a paradigm for how we should address the issues raised by the availability of other medical tests in the future, or does AIDS warrant a unique response?

Current and future use of medical testing to determine health care insurability, and the impact that such use of medical tests by private health insurers could have on public financing of health care, prompted the request for this study by the House Energy and Commerce Committee, its Subcommittee on Health and the Environment, and the Subcommittee on Intergovernmental Relations and Human Resources of the House Government Operations Committee. The request was supported by the Subcommittee on Health of the House Ways and Means Committee and by the Subcommittee on Natural Resources, Agriculture Research, and Environment of the House Committee on Science, Space, and Technology.² (Two activities conducted as part of this assessment have been previously published.³)

²A letter of support for the study was also received from Senator Daniel K. Inouye (D.-Hawaii).

³*AIDS and Health Insurance: An OTA Survey* (February 1988) and *The Impact of AIDS on the Kaiser Permanente Medical Care Program (Northern California Region)* (July 1988).

HEALTH INSURANCE UNDERWRITING

Group v. Individual Insurance

The purpose of insurance is to minimize financial losses that may arise from unexpected events. Insurance operates by spreading risks over a number of people so that many individuals who could have a loss, but don't, help pay for the losses of the few that do sustain losses. Insurance works on the principle that there must be uncertainty that a loss will occur, and that the loss is beyond the control of the insured. The size of the potential loss is another factor and should ordinarily be of such magnitude that its occurrence has a significant financial impact on the insured. Private

insurance operates on the principle that the cost of insurance generally should be proportional to the risk involved. Individuals whose potential losses are large are expected to pay more in premiums than those whose potential losses are likely to be less.

Although individual and group health insurance provide protection against similar types of medical expenses, they are, in a sense, fundamentally different types of insurance. An individual health insurance contract is one made by an insurer with an individual applicant and normally covers that individual, and, in some cases, his or her depen-

dents. A group insurance contract is made with a sponsor, usually an employer, and the group sponsor, not the members of the group, is the insured party. Group insurance contracts are, as a rule, continuous in nature and ordinarily continue beyond the lifetime or membership in the group of any of its individual participants.

Group insurance is generally issued without medical information or other evidence of insurability of the individuals covered, and group underwriters are usually interested only in whether the group as a whole can be insured. Group underwriters will accept groups whose expected claims experience meets the standards established by an insurer for a plan of benefits and will set a rate to cover those expected costs. As noted earlier, larger groups are generally experience-rated, meaning that the premiums charged are based on the actual amount of claims payments made on behalf of the group in a prior period, usually the preceding year. In contrast, applicants for individual insurance are not part of a well-defined, homogeneous, and generally healthy group; and individuals are also free to apply for various types and amounts of coverage. The fundamental purpose of underwriting is to assure that insured persons within each risk class have the same probability of loss and probable amount of loss. Thus, "medical underwriting" is customarily used by most insurers to determine whether and under what terms individual insurance coverage will be approved.

Adverse Selection

"Adverse selection" refers to the situation whereby, in the absence of any controls, persons who seek to obtain insurance will tend to be those who will use it the most; that is, those with a greater than average probability of loss. Applicants who are motivated to purchase coverage because they are aware of a medical problem that is not yet evident to the underwriter can select against the insurer. This is of concern in both group and individual insurance markets, but particularly in the latter. Group insurers try to protect themselves against adverse selection by using certain group underwriting techniques. For example, group insurers usually write coverage only

for groups that exist for reasons other than for the purpose of obtaining insurance. There generally is a flow of members into and out of such groups so that the average age and therefore the average risks of these groups do not increase much over time. Employer-based groups are especially attractive to insurers, because employees whose health is good enough to meet employment standards are generally better-than-average risks for insurance purposes.

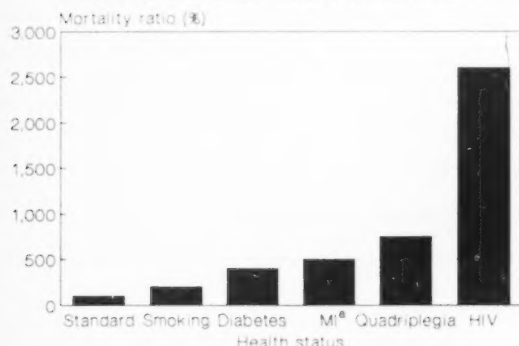
Adverse selection is a particular problem for the individual insurance market. Although most applicants are seeking coverage for the costs of unknown or unpredictable diseases, some applicants are especially motivated to obtain insurance, because they know they may have a higher than average probability or even a certainty that they will require medical treatment.

Underwriting Factors

The goal of the underwriter is to determine whether and on what basis insurance can be issued at "standard" rates, offered at higher premium rates or with other limitations (such as excluding a specified medical condition from coverage), or whether insurance should be refused (declined) altogether. Each insurer prescribes its own range of acceptable risk selection factors.

For health insurance, age and current and future health status are the two most important risk factors. Claims costs for different benefits often vary by gender, so sex is also a factor. Most health insurers deny any applicant whose probability of disease exceeds three times the standard risk for his or her sex and age, and most life insurers will refuse an applicant whose risk of death exceeds five times the mortality risk of a person with no health impairment. HIV infection, for example, far exceeds the limit of insurability for both life and health insurance. Insurers estimate that the mortality risk of an HIV-infected person is 26 times that of a standard risk (figure 1-1), and that the mortality risk of an asymptomatic 35-year-old male infected with the AIDS virus is 44 times that expected for a healthy, non-HIV-infected 35-year-old male.

Figure 1-1.—Comparison of Mortality Risks for HIV Infections and Other Selected Conditions



*Myocardial infarction.

SOURCE: K. Clifford and R. Iuculano, "Acquired Immunodeficiency Syndrome (AIDS) and the Recommendations of the NAIC Advisory Committee on AIDS," statement to the Health Insurance (B) Committee of the National Association of Insurance Commissioners, Orlando, FL, Dec. 9, 1986.

Two types of information are obtained from applicants for individual coverage. First, is the health history. A history of past illness or accident will be given weight depending on the severity of the original ailment, degree of permanent impairment (if any), possibilities of recurrence, complications that may develop, etc. Individuals with conditions that are chronic often have high costs and large claims and may be refused coverage. Certain family health information may be requested relating to the health of relatives that may have some bearing on the applicant's health (e.g., family history of diabetes). Second, the applicant's current physical condition is evaluated. Depending on this assessment, certain tests or studies may be requested (e.g., blood chemistry, urinalysis, electrocardiogram), depending on the age or kinds of coverage sought.

Regulation of Insurers

All of the States have established laws that require insurance companies to meet a variety of financial and other requirements in order to obtain a license to do business in each State. The general framework is similar, but the exact requirements vary widely from State to State. Certain amounts of financial resources needed to establish solvency as an insurer are ordinarily stipulated. Many States also require companies

to maintain membership in a guarantee association, including financial participation in such an arrangement to cover the liabilities of impaired or insolvent companies.

While the substance of State regulation is similar to that of commercial insurers, hospital service (Blue Cross) and medical service (Blue Shield) plans are ordinarily exempted from State commercial insurance laws and are granted franchises to do business and are regulated under separate enabling legislation. In response to growing competitive pressures, an increasing number of BC/BS plans are seeking legislative approval to reorganize themselves as mutual insurance companies.

Group health insurance rates are based on past experience ("experience-rated"), and health insurance underwritten on a group basis has a history of being quite competitive. Regulation of individual health insurance contracts is somewhat more rigorous and also more standardized than for group contracts. This is due, in large part, to the view that the people who are individually insured lack expertise about many insurance matters and are not in a position to negotiate the terms of contracts with the companies that specialize in this field.

Some States require the advance approval of individual policies and related contractual materials (e.g., the application form). In many States, although information is provided to the insurance department, these materials will be deemed approved unless advised to the contrary within a specified period of time.

States frequently prohibit certain types of discriminatory practices in issuing, continuing, or canceling insurance policies, or prohibit charging higher premiums solely because of certain physical handicaps such as blindness, mental handicaps, etc., unless the discrimination can be justified by sound actuarial practice.

Many States have also adopted various mandated benefit laws. Alcoholism, drug addiction, and maternity coverage are frequently required. Some States require insurers to offer prospective buyers certain benefits, but the inclusion of those benefits in group contracts is often not mandatory.

Many States also have laws governing some aspects of group insurance contracts, such as who constitutes a group for group benefit purposes. Many States have also adopted laws requiring group contracts to contain certain types of mandatory conversion and/or continuation-of-coverage provisions, which permit members (and dependents) of a group to continue their insurance protection on an individual basis when their coverage under a group plan ceases. The continuation is an extension of the original group plan at the same premium, though the separated group member pays the full premium costs of coverage, including any employer contributions made on behalf of members still in the group. (The Federal Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Public Law 99-272) has a similar provision regarding continuation of coverage.)

States impose taxes on premiums received by insurance companies. These taxes vary from State to State, by the type of company involved, and whether the insurer is an out-of-State or domestic company. Most of the tax rates are in the 2 to 2.5 percent range. Most States do not impose premium taxes on BC/BS plans, though several States do impose some charges on them in lieu of premium taxes.

While the McCarran-Ferguson Act (Public Law 15, 79th Congress) provides that the States have the major regulatory responsibilities with regard to the business of insurance, several Federal laws affect health benefit plans, particularly group plans. Under the Federal tax code, employer contributions for health benefits are excluded from the taxable income of their employees. Legislation such as the Employee Retirement Income Security Act (ERISA), the Health Maintenance Organization (HMO) Act, and Medicare, each affect the design of many private health benefit programs. Congress has also enacted laws prohibiting certain discriminatory practices relating to age and sex in the provision of health benefits for employees and their dependents. And as mentioned above, the tax laws and ERISA were recently amended under COBRA to require that most group benefit plans continue coverage for workers and their dependents who would lose such protection due to job termination, death, divorce or

legal separation, and for certain other qualifying events.

The most important competitive development in the group health benefits market during the last 15 years has been the movement toward self-insurance by large employers. Self-insured plans offer several key advantages to employers. Employers are able to use and retain earnings on amounts that would otherwise be paid to and held by insurers to create claims reserves. No premium taxes are applied to self-insured plans. Most importantly, self-insured plans can avoid the requirements of State insurance laws and regulations because of the Federal ERISA legislation. Thus, much of the group benefits marketplace is virtually unregulated by the States. Self-insured plans need not comply with any of the State laws that require health insurance contracts to include specific benefits or comply with anti-discrimination restrictions applied to insured plans, need not pay State insurance premium taxes, and need not participate in State insurance pools for high-risk individuals.⁴

Results of the OTA Survey

Insurance testing for HIV infection has generated much controversy and disagreement among insurers, insurance regulators, insurance applicants, legislators, and other policymakers. Yet, there is little information on who insurers test and what tests they require. OTA therefore conducted a survey of commercial insurers, BC/BS plans, and HMOs in the summer and early fall of 1987. The OTA survey was an attempt to provide a view of HIV testing in the context of other routine tests required by health insurers and had a twofold purpose: 1) to collect basic information on underwriting practices and the use of medical screening by health insurers; and 2) to document how health underwriters are responding to the AIDS epidemic.

Approximately 14.5 million individuals under age 65 (and their family members, when covered) have health insurance without the benefits of group membership. These are the individuals that must

⁴See app. B in the full report for a description of State high-risk insurance pools.

meet underwriting standards to obtain health coverage, and their insurers were the focus of the OTA survey. Commercial companies insure 9.3 million; BC/BS plans, 4.2 million; and HMOs, 1 million.

The survey was sent to 88 commercial insurers who comprise 70 percent of the commercial, individual health insurance market; to 15 of the 77 BC/BS plans; and to the 50 largest local and national HMOs in the United States. Seventy-three of the 88 commercial insurers responded, although only 62 met the survey requirements; approximately 57 percent of the commercial, individual health insurance market is represented in the survey findings. All 15 BC/BS plans completed the survey, and 39 of the 50 HMOs responded, but only 16 reported that they allow individually underwritten enrollment. Overall, 84 percent of the commercial carriers, BC/BS plans, and HMOs that were surveyed responded.

Medical and Other Factors in Risk Classification

Approximately three-quarters of individual and small group applications for commercial health insurance were classified as "standard" by the responding insurers and obtained coverage without extra premiums or special limitations. Twenty percent of individuals and 15 percent of small group members were rated as "substandard" and issued policies that exclude preexisting medical conditions, had a higher than standard premium, or both. The exclusion may be for a specific condition, such as gallstones, or for an entire organ system, such as reproductive disorders. Finally, 8 percent of individual and 10 percent of small group applications were judged uninsurable and denied coverage. Most serious diseases were uninsurable, including severe obesity, diabetes mellitus, emphysema, alcoholism, coronary artery disease, cancer, schizophrenia, and AIDS.

Risk classification by the responding BC/BS plans was similar to the commercial approach except for four "open enrollment" plans that accepted all applicants regardless of health status. The respondents accepted 83 percent of individual applicants as standard, 9 percent with substandard policies, and denied coverage altogether to 8 percent. Sixty to 100 percent of small group

applicants were also accepted as standard by half the plans, and up to 25 percent were denied.

HMO risk classification differed from the others. Federally qualified plans are restricted to either accepting applicants at a community rate or denying membership altogether. As a result, exclusion waivers and substandard premiums are not common. The responding HMOs, however, were no more willing to underwrite high-risk applicants than the commercial insurers or BC/BS plans. They accepted 73 percent on a standard basis and denied membership to 24 percent of individual applicants.

Other factors besides ill health can seriously hamper access to commercial health coverage by individual applicants and their family members. Dangerous health habits (e.g., drug abuse), suspected criminal association or unethical behavior, age, occupation, and financial status were most commonly cited by commercial insurers as critical to determining insurability. Healthy habits, such as nonsmoking, were also rated as important, an indication of the increasingly common use of premium credits for nonsmokers. Place of residence was an important factor to a significant minority of commercial insurers, mostly due to concerns about insurance fraud known to occur in certain localities and because of regional variations in health care costs. Contrary to guidelines proposed by the National Association of Insurance Commissioners (NAIC), 18 companies used sexual orientation in underwriting, and 5 of these companies considered it important or very important. (These 18 companies held approximately 10 percent of the individual, commercial health insurance market. Five were among the 25 largest in the country.) Three companies requested an attending physician statement (APS), and two ordered a physical exam based on sexual orientation. It is unclear how insurers ascertained an applicant's sexual preference. Most of the respondents (48 of 61) provided samples of their health insurance applications, none of which included any questions concerning sexual orientation or lifestyle.

In contrast, BC/BS insurability was almost purely a question of medical condition. All the responding BC/BS plans, except the four that hold

open enrollment, rejected some applicants in poor health. Nearly half of the plans denied nongroup applications because of alcohol or drug abuse. No BC/BS plan reported using sexual orientation in underwriting.

Access to HMO membership was fundamentally a matter of health status as well. However, age, type of occupation, health enhancing behavior (e.g., nonsmoking), and sexual orientation were also considered key to insurability by 19 percent or more of the responding plans. As in the case of the commercial carriers, it is not clear how sexual orientation was identified by the four HMOs that considered it a key underwriting factor.

Health insurance applicants were rarely subjected to physical examinations and medical tests. Only 4 percent of individual and 2 percent of small group applicants to the responding commercial insurers were required to have a physical exam or some type of blood and/or urine test. Just two of the BC/BS plans required physical exams; one also required medical tests for some of its individual and small group applicants. Only three of the HMOs sometimes required physical exams or medical tests.

Beyond the health information provided directly in insurance applications, information provided by the applicant's physician (the "attending physician's statement," or APS) was the most common supplemental source of information. The commercial carriers required an APS for 20 percent of individual and 18 percent of small group applicants. Late applicants to large groups were also often required to furnish an APS. Almost three-quarters of BC/BS plans ordered a physician statement for at least 30 percent of their individual applicants, and more than half required an APS for up to 40 percent of small group applicants. Half or more of the responding HMOs requested an APS for 10 to 85 percent of their nongroup applicants and 10 to 20 percent of small group applicants. In fact for most applicants, in lieu of ordering a laboratory test for medical reasons, traditional insurers and HMOs alike usually relied on the test results reported by the applicant's physician. HIV testing was an exception in a few cases: three responding commercial carriers required an HIV test on every

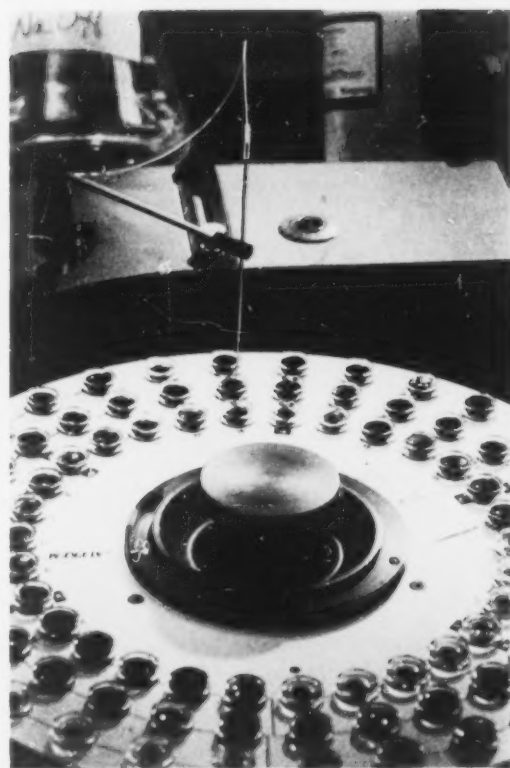


Photo credit: Hoffman-La Roche Inc., Nutley, NJ

Automated testing procedures include a volume fill check, one of several quality control measures to ensure exactly the right amount of reagent in each bottle.

applicant in areas of high prevalence, such as New York and California.

AIDS Policies

Fifty-one (86 percent) of responding commercial insurers either screened or planned to screen individual applicants for HIV infection; 41 already did it and 10 planned to. Efforts to identify high-risk group applicants were also common. Twenty-seven small group (77 percent) and 11 large group insurers (58 percent) either screened or planned to screen through some method. The most common approach was by incorporating questions in the health history portion of the application. Asking AIDS-related questions is necessary to screen out preexisting conditions. If an applicant knowingly misrepresented his or her health condition

(e.g., recognized symptoms of AIDS or fully diagnosed AIDS or AIDS-Related Complex (ARC)), the insurer may have grounds for denying reimbursement for the condition or rescinding coverage altogether. An admission of AIDS, ARC, or HIV seropositivity results in immediate denial of the application. Forty-two companies (82 percent) request a physician statement for selected, individual applicants in order to determine the presence of AIDS symptoms or other risk factors. (The APS may contain the applicant's HIV status as well.) Eighty-one percent of small group (22 of 27) and 64 percent (7 of 11) of large group insurers also screen this way. HIV testing was also quite common. Thirty-one companies routinely tested individual health insurance applicants for HIV antibodies; of these, 7 tested all applicants, 14 tested only those considered to be "high-risk," and 10 tested according to various criteria (e.g., State of residence, medical history, policy amount, etc.). All those who tested use the ELISA-ELISA-Western blot series. In States and localities where HIV testing is prohibited, 17 insurers required T-cell subset studies as a substitute. HIV testing is less common among the responding group insurers; only 9 of the small group (33 percent) and 3 of the large group insurers (27 percent) require an ELISA and Western blot for some applicants. T-cell subset studies are also used by 6 small group (22 percent) and 3 large group insurers (27 percent).

Eleven of the responding BC/BS plans either screened or planned to screen individual applicants for AIDS or ARC-related diagnoses; of these, eight already did, and three planned to. BC/BS efforts to identify high-risk group applicants are also common. Ten small group (77 percent) and seven large group plans (54 percent) either screened or planned to screen through some method. Eleven plans ask an AIDS-related question in their nongroup applications. If applicants answer that they have had or have been treated by a physician for AIDS or ARC, coverage is denied. As in the case of the commercial insurers, BC/BS plans ask about AIDS to screen out preexisting conditions. In addition, nine plans (82 percent) may ask for an APS to help evaluate a nongroup applicant's risk for AIDS. Seventy percent of small group (7 of 10) and 57 percent of large

group plans (4 of 7) also order an APS for this reason. Only one BC/BS plan intended to test high-risk applicants for HIV infection.

Half or more of the responding HMOs screened or planned to screen individual (8 of 15) and small group applicants (4 of 8) for infections with the AIDS virus by one method or another. Three of the plans that do not are prohibited from doing any medical screening by State law. All the plans that screen ask an AIDS-directed question in the health history portion of their enrollment form. As in the case of the commercial insurers and BC/BS, an admission of AIDS, ARC, or HIV seropositivity results in denial of the application, and the AIDS-related questions on the application are used to screen out preexisting conditions (where allowed). Six plans request an APS to help determine an individual applicant's risk for AIDS; two plans similarly screen small group applicants. HIV testing of high-risk, individual applicants is done by only two plans and was under consideration by a third. No plan reported testing group applicants or using the T-cell subset test.

AIDS Claims Experience and Cost Projections

Forty-five commercial insurers had reimbursed at least one individual policyholder for AIDS-related care. More than half of the respondents reported 10 AIDS cases or less, while 4 had reimbursed more than 50 individuals. On average, each insurer covered the care of 22 AIDS-related cases. (Of the remaining responding insurers, 6 reported no AIDS-related cases, 10 were unable to report their experience, and 1 had recently withdrawn from the individual market.)

Of the 20 insurers providing AIDS case data for their small group policies, 6 reported no AIDS-related cases and 14 had from 1 to 50, totaling 146. Twenty-two large group insurers reported 613 AIDS-related cases; 3 had no cases, 12 had less than 10, 6 had 11 to 60, and 1 company alone had 350.

Twenty-one individual insurers provided projections of AIDS-related claims costs for 1987, forecasting total claims of \$11.04 million for individual health insurance, an average of \$0.53 million per insurer. Two companies did not expect any AIDS cases in 1987—both specialize in insur-

ance for seniors—while four projected costs of \$1.3 to \$2.3 million for individual health policies. (Cost projections were not furnished by 40 companies.) Twenty-two insurers who had received at least 1 AIDS-related claim reported linking no one with a preexisting condition for AIDS; 11 found 1 to 9 percent of cases to be preexisting; 10 companies, 10 to 50 percent; and 2 companies, more than 60 percent.

Seven small group insurers forecast a total of \$1.5 million AIDS-related costs for 1987, ranging from none at one firm up to \$618,000 at another. Seven large group insurers projected a total of \$489,000 and an additional company reported that it expected 1987 AIDS-related group claims to total \$5 million to \$10 million.

Ten BC/BS plans reported reimbursing 3,933 subscribers for AIDS-related care, an average of 393 subscribers per plan (although one plan alone accounted for 3,000 cases). (The BC/BS plans' AIDS case and cost data reflected both individual and group policy experience.) The 7 plans that never hold open enrollment reported a total of 453 AIDS-related cases, an average of 65 subscribers per plan. Three of these plans are located in areas of high AIDS prevalence. In contrast, the 3 plans that are continuously open (and thus never screen) reported reimbursing 3,480 subscribers for AIDS-related care, an average of 1,160 cases per plan. Two of these plans are in areas of high AIDS prevalence, and all three have held large market shares. Only five plans provided 1987 projections of AIDS-related costs. Three non-open enrollment plans (two are located in high prevalence areas) forecast a total of \$29.6 million in AIDS-related claims for 1987. Claims totaling \$27 million were projected by two open enrollment plans; \$20 million at one plan alone. Eight of the 10 plans that have identified at least 1 subscriber with AIDS reported finding that 1 to more than 50 percent of these subscribers had a preexisting condition for AIDS. Two of these plans, both in areas of high AIDS prevalence, connected more than half of their AIDS cases with a preexisting condition.

Twelve HMOs reported 1,468 members with AIDS or ARC, an average of 122 members per HMO. The range varied from none at 2 HMOs to 940 patients at 1 HMO. (The HMOs' AIDS case and cost data reflect their individual and group membership experience.) Only two HMOs provided projections of AIDS-related costs for 1987. One plan that had identified 10 cases during the first 10 months of 1987 forecast total costs of \$750,000 for the year; the other had 11 cases in the year preceding September 1987 and forecast total costs of \$700,000 for 1987. (An additional HMO did not project 1987 costs but estimated that its diagnosed members had average lifetime costs of approximately \$35,000.) One HMO, located in a high prevalence area, reported that more than half of its individual members with AIDS or ARC were found to have a preexisting condition. According to State law and in contrast to the other insurers, this plan was obligated to provide services for preexisting conditions (without a waiting period) unless the applicant had deliberately misrepresented his or her health status before joining the HMO.

The commercials, BC/BS plans, and HMOs reported similar methods to reduce their exposure to the financial impact of AIDS. These activities included reducing exposure to individual and small group markets by tighter underwriting guidelines, expanding the use of HIV and other testing, adding AIDS questions to the enrollment applications, and denying applicants with a history of sexually transmitted diseases. Two commercial insurers intended to place dollar limits on AIDS coverage in new policies, and another was introducing a waiting period for AIDS benefits. One HMO intended to withdraw from the individual health insurance market altogether, and a commercial carrier reported withdrawing from the District of Columbia. A BC/BS plan intended to lengthen the waiting period for new subscribers with a history of hepatitis, lymph disease, and mononucleosis, and two others were expanding their AIDS education efforts.

TESTING BY EMPLOYERS

There are reasons other than concern over health care costs for which employers might want to screen their prospective as well as current employees. First, screening may be used as part of a preemployment evaluation to disqualify applicants (e.g., testing for illegal drug use) or to determine if the applicant can physically perform the intended work (e.g., examinations for firefighters and police). Second, after a person is hired, screening may be used to determine whether there is any health condition that may require special precautionary care because of workplace exposures. Third, screening may be used to monitor workers exposed to known or suspected environmental hazards, including preplacement testing to establish a baseline that can be used for comparison with future worksite monitoring results. Finally, screening may be incorporated into workplace wellness programs to identify risk factors associated with certain diseases so that these factors can be reduced through health education.

Incentives to screen prospective employees may be much more significant for some employers than for others. Employers with low turnover and high training costs may be especially interested in preemployment screening. Similarly, employers with generous health care and disability benefits may be more inclined to screen than employers with limited benefits. On the other hand, employers with high employee turnover may not have incentives to test for disease susceptibilities if new employees are young and likely to be employed elsewhere when these diseases become manifest. However, these same employers might have greater incentives to test for illegal drug use because of greater use among younger workers.

A wide variety of legal restraints is potentially applicable to employment-based screening, although much remains unsettled in this area. Distinctions must also be made as to whether the employer is in the public or private sector (i.e., whether governmental action is involved); whether a cause of action by a prospective employee who objects to testing is grounded in an existing statute or in case law as developed over the years by the courts; and for employees, whether or not they

are represented by unions and have the additional protection of collective bargaining agreements. Additionally, States differ in their approaches and available legal remedies, so the State in which a cause of action is brought may also have a substantial bearing on the success or failure of challenges to testing.

The principal statutory remedy available to persons objecting to employment-based testing is the Vocational Rehabilitation Act of 1973 (29 U.S.C. sections 701-796), which applies to Federal employment and to employers who receive Federal funds. In addition, over 40 States and the District of Columbia have legislation prohibiting handicap discrimination in private sector employment, and while the definitions and judicial interpretations of what constitutes a handicap vary by State, about one-third follow the Federal law.

Handicapped persons must be hired or continue to be employed if they can be reasonably accommodated and can perform their work without endangering the health and safety of other workers. In March 1987, in the case of *School Board of Nassau County, Florida v. Arline*,⁵ the United States Supreme Court ruled that a person with tuberculosis was a handicapped person within the meaning of the law and that contagiousness did not automatically remove the person from the Act's protection. The Court, however, expressly stated that it was not ruling on whether a person infected with the AIDS virus but without disease would come under the Act's protection.

The Extent of Employment-Based Medical Testing

Physical Examinations

Perhaps the most prevalent type of medical screening used by employers is the general physical examination, including the use of blood chemistry profiles and urinalyses of the same types used by the insurance industry. For example, according to surveys by the National Institute for Occupational Safety and Health (NIOSH), the per-

⁵107 S.Ct. 1123, reh. denied, 107 S.Ct. 1913 (1987).

cent of employers who require job applicants to pass medical screening exams increased from 38.5 percent in the early 1970s to 49 percent in the early 1980s. These exams seem oriented toward improving or maintaining the employee's health, because companies with industrial hygiene and safety programs, and/or unionized companies, are more likely to provide medical screening than other companies.

The use of physical exams and medical testing is associated with company size and type of business. The larger the company, the more likely that physical exams and screening tests will be conducted. Employees in transportation and public utility industries are most likely to have preemployment examinations; in 1981-83, an estimated 73 percent of employees in these industries were screened, followed by 69 percent in the services industry, and 62 percent in the manufacturing industry. In 1981-1983, an estimated 36 percent of employees had blood tests, and 35 percent had urine tests. In plants employing more than 500 workers, periodic medical screening included blood and urine testing for 69 and 66 percent of all workers, respectively. Blood testing was most prevalent in the service industries, where an estimated 60 percent of workers were screened.

Genetic Testing

Genetic testing to screen individuals for hypersusceptibility to hazardous materials has been controversial, because genetic traits frequently are associated with particular racial or ethnic backgrounds.

In a 1982 OTA survey of the 500 largest U.S. industrial companies, 50 of the largest private utilities, and 11 large labor unions, only 6 of the 366 organizations who responded to the survey were then conducting genetic testing, 17 had used some of the tests in the past 12 years, 4 anticipated using the test in the next 5 years, and 55 thought it possible that they would use the tests in the next 5 years.

In a 1986 OTA survey of 120 biotechnology companies that were developing or likely to develop genetic tests for commercial use, of 85 respondents, 12 were developing or planned to develop tests for human genetic conditions. Of these

12 companies, employment-based testing and insurance testing were far down the list of possible uses. In descending order of importance, these companies rated likely sites of use as: genetic clinics; health department clinics; health department screening programs; prepaid health groups; private primary care practices; and sites such as reference and DNA labs, insurance companies, the military, places of employment, private non-genetic specialty practices, correctional institutions, public schools, and homes.

Drug Use Testing

Various surveys have documented the increasing tendency of both private and public sector employers to screen applicants and to test employees for use of illegal drugs. Based on these surveys, perhaps half or more of employers, especially large employers, now test or plan to test for drug use. For example, of the Fortune 500 companies, urine drug testing for job applicants and/or current employees increased from 10 percent in 1982, to approximately 25 percent in 1985, to an expected 50 percent in 1987.

In a 1986 survey by the College Placement Council, whose members recruit on college campuses, the most common reasons given for drug testing were concerns over workplace safety (by far the most important reason); security; quality/reliability of products; quality of service; increased productivity; control of medical costs; and law, government, or noncompany regulations. The types of employers most likely to test job applicants were utilities (37.1 percent); chemicals, drugs, and allied products (9.3 percent); aerospace (8.6 percent); and petroleum and allied products (7.9 percent). Nearly all screened all applicants, whether for management, clerical, or technical positions, and most screened applicants whether they were seeking full-time, part-time, or temporary positions.

These trends are found among both private and public sector employers, including the Federal government.

AIDS Antibody Testing

According to the Centers for Disease Control (CDC), there is no justification for excluding



Photo credit: Home Office Reference Laboratory, Shawnee Mission, KS

A rapid flow analyzer used for the quantitative determination of glucose in human plasma.

AIDS or antibody-positive individuals from the workplace on the grounds of risks to coworkers, and CDC also recommends against routine testing in the workplace.

Except for a few employers who have tested job applicants and/or employees for infections with the AIDS virus, employers have generally rejected AIDS antibody testing and support education as the best way to deal with AIDS among their employees. There appears to be a relationship between support of testing and knowledge of the ways that AIDS can be spread. There is also a substantial gap between what employers say should be done versus actually developing educational strategies and programs for their employees. For example, in one survey (by the magazine,

Business Week) in early 1987, employers were asked what they would do if a coworker objected to working with an employee with AIDS. Eight percent of respondents said they would move the employee with AIDS; 14 percent would move the coworker; 29 percent would insist that the situation continue unchanged; 3 percent would take none of these actions; and 46 percent were not sure what they would do.

Employers who have had to face AIDS among their employees have generally treated AIDS as they have treated other illnesses. Many employers who find they have employees with AIDS try to accommodate those individuals so that they can continue to work as long as possible and keep their health benefits coverage through the company's health plan.

Most businesses have not yet taken action to monitor employees with AIDS because most have not had experience with such employees. However, there are indications that AIDS-related health care costs (and disability and life insurance costs) may be increasing for some employers to the point that employer attitudes may change. The costs of treating AIDS was not a major issue for employers in 1985. By the next year, 1986, among 1,500 surveyed businesses in 36 States representing 4.4 million employees, 3 percent of responding employers were measuring the cost impact of AIDS, and 2 percent indicated they were modifying the design of their health plans. By late 1987, surveyed companies with AIDS among their employees reported an increase of 4.5 percent from AIDS in their expenditures for health care, and expected AIDS-related care to increase their health care expenditures an additional 16 percent by 1990. (The highest percentage increases among these companies were for life insurance costs, up nearly 28 percent from AIDS, but employers expected to gain more control over these costs so that increases in life insurance costs would be limited to 7 percent by 1990.)

Additional pressure on employers' health care costs from AIDS among their employees comes at a time of extreme health care cost-consciousness on the part of businesses. With the high rates of health care cost inflation since the mid-1970s and the increased health insurance premiums that have

accompanied these rates, employers have sought ways to shift more of the costs to their employees. Surveys have shown that many employers have increased their employees' share of health care costs and modified health plans to encourage use of less costly services, and more large employers are turning to self-insurance instead of purchasing health insurance through insurers.

The rapid growth of self-insurance does raise special concerns related to medical testing in the

workplace. Because there is little regulation of self-insured health plans, medical conditions such as AIDS could affect employees of self-insured employers differently than employees of employers with conventional insurance, because self-insured employers have different means of responding to the problems of high-cost employee health benefit claims.

DIAGNOSTIC AND PREDICTIVE MEDICAL TESTING

Tests Currently Used by Insurers

Information on the types of medical screening tests used by insurers is based on testing of both life and health insurance applicants. The great majority of testing is in the life, not health, area, because individual life insurance applicants greatly outnumber individual health insurance applicants.

Most of the tests used by insurers are commonly used by clinicians and include blood biochemical profiles and routine urinalyses. Both blood biochemical profiles and urinalyses are mainly directed at uncovering evidence of underlying kidney, liver, and cardiovascular diseases, and diabetes. However, when applied to asymptomatic populations, these tests are not very predictive of disease. For example, in the case of serum glucose, although approximately 2 percent of asymptomatic adults have repeatedly elevated values, less than 17 percent are found to be diabetic. Because of their poor predictive value, professional guidelines recommend that they be administered on the basis of clinical findings. There is evidence that commercial insurers are limiting the use of biochemical profiles and urinalyses to selected high-risk applicants.

Insurers may also screen for evidence of use of specific prescription drugs, for drugs of abuse, and more recently, for evidence of infection with the AIDS virus.

There are two reasons to screen for prescription drug use: 1) to indicate the level of patient compliance with medically prescribed treatment—

i.e., whether the applicant is in fact using the medications his or her physician has prescribed; or 2) as evidence that an applicant is undergoing



Photo credit: Abbott Laboratories, North Chicago, IL

Preparation of samples for abused drug testing.

treatment for a medical condition he or she has not divulged on the medical questionnaire. The most common medications tested for are drugs to treat cardiovascular diseases such as hypertension and heart disease (e.g., diuretics and beta-blocker drugs) and diabetes (e.g., hypoglycemic or blood-sugar-lowering drugs).

The most frequently tested drugs of abuse are nicotine and cocaine, with the nicotine test used to confirm that applicants are nonsmokers because of the increasing use of nonsmoker discounts (for life insurance applicants) by insurers. Abusers of illegal drugs are considered uninsurable by many companies.

Tests to detect evidence of infection with the AIDS virus are also being used. In 1986 the Home Office Reference Laboratory, Inc. (HORL), the principal lab used by life and health insurers, performed more than 128,000 tests for antibodies to the AIDS virus, using the ELISA screening test and the Western blot confirmatory test for ELISA-positive blood specimens. HORL also performed more than 25,000 T-cell tests, one of the tests that is used to indicate immune function status and used by insurers where use of AIDS antibody testing is prohibited (principally California). During this same period, HORL performed 213,000 routine blood tests. Thus, if we assume that persons who had HIV antibody or T-cell testing also had routine blood testing performed, approximately 70 percent of persons undergoing blood testing by the insurer clients of HORL were also tested for signs of infection with the AIDS virus.

The types of blood and urine tests conducted by HORL for insurers in 1986 are summarized in table 1-2.

Tests of Interest Because of High Prevalence and Physician Screening Practices

Tests to predict cancers and heart disease or to uncover these diseases in their latent stages may be of interest to insurers.

Screening tests for latent disease are available for several of the most common cancers; such as, colon, breast, and uterine/cervical cancers. However, although effective in reducing mortality

when applied to age-appropriate populations, most available screening tests will miss a significant percentage of individuals who should test positive (referred to as a test's "sensitivity"), and conversely, will be positive in many individuals who do not have the indicated disease (a test's "specificity"). Furthermore, the follow-up tests required to correctly identify those with cancer are expensive and invasive.

For example, tests to detect occult blood in the feces are estimated to detect only 25 to 35 percent of colon polyps and only 70 to 90 percent of colon cancers. Furthermore, of the positive tests, only 52 percent would represent true cases of either polyps (40 percent) or cancer (12 percent). Although the test is inexpensive to administer and interpret, a positive result would need to be further evaluated by direct and/or indirect visualization of the colon through sigmoidoscopy/colonoscopy and/or air-contrast barium enema x-ray studies. The costs of evaluating a positive result can therefore be as high as \$1,000. Because of the relatively low accuracy of the fecal occult blood test, the American Cancer Society recommends that, in addition to occult blood testing, persons over 50 years of age have yearly sigmoidoscopies for 2 years, followed by similar exams every 3 years.

Available tumor marker assays could be used to identify applicants with cancer. For example the carcinoembryonic antigen (CEA) test is positive in more than 80 percent of advanced-stage colon cancer and 40 percent of early-stage cancers. However, the test is not very predictive of disease. When applied to asymptomatic populations, only 12 percent of positive tests represent CEA-associated cancers. However, sources of false positive results include hepatitis, ulcerative colitis, gastric ulcer, and renal disease, all of which would likely lead to exclusion or coverage on a non-standard basis. Although these markers have been available for many years, they have not been adopted by insurers, because they are not accepted as screening tests by the medical profession.

A new test is being investigated that may be applied as a universal screening tool for cancer. The test is based on differences found between the

Table 1-2.—Blood and Urine Tests Used by Commercial Insurers (as reported by Home Office Reference Laboratory)

Blood tests	Associated conditions
Glucose	Increased glucose associated with diabetes mellitus, glucagonoma, mineralocorticoid excess (many causes), and hyperthyroidism.
Blood urea nitrogen (BUN)	Increased BUN associated with primary renal disease (e.g., medullary cystic kidney, hereditary nephritis), secondary renal disease (e.g., infectious, immunologic, vascular, metabolic, obstructive), and prerenal azotemia.
Creatinine	Increased creatinine associated with abnormal kidney function (see BUN).
Uric acid	Increased uric acid is associated with gout, renal failure, myeloproliferative disorders, and leukemia.
Total protein	Increased total protein is associated with systemic infection (e.g., tuberculosis), systemic inflammation (e.g., collagen vascular disease), malignancy (e.g., lymphoma, myeloma), and liver disease (many causes).
Albumin/Globulin	Decreased albumin is associated with malnutrition, nephrotic syndrome (many causes), protein-losing enteropathies (many causes), severe liver disease (many causes).
Aspartate aminotransferase (AST, formerly serum glutamic-oxaloacetic transaminase or SGOT)	Increased AST is associated with hepatocellular inflammation (many causes), cardiac inflammation (e.g., infarction, myocarditis, pericarditis), skeletal muscle inflammation (e.g., viral infection, polymyositis).
Alkaline phosphatase	Increased alkaline phosphatase is associated with liver disease (many causes), bone disease (many causes).
Glycohemoglobin (HBA1c)	Glycohemoglobin test measures the percentage of hemoglobin molecules that have glucose attached to them. Glycohemoglobin measurements indicate blood sugar activity during the six to eight weeks prior to the test and are therefore a measure of the success or failure of diabetic management. Test may be used as a diabetes screening test among asymptomatic individuals.
Bilirubin	Elevations associated with liver disease (e.g., cirrhosis), gall stones, pancreatic cancer, and some anemias.
Alanine amino transferase (ALT, formerly called SGPT or serum glutamic pyruvic transaminase)	Elevations associated with heart muscle damage, liver cell destruction, pancreatitis, infectious mononucleosis, some muscle diseases, and rickettsial infections.
Gamma-glutamyl transpeptidase (GGT)	A sensitive (but non-specific) indication of liver function. Elevations associated with alcoholism, recent myocardial infarction (within one month), cholestasis, nonalcoholic liver disease, and porphyria cutanea tarda.
Cholesterol	Increased cholesterol is associated with primary (e.g., familial) and secondary (e.g., hypothyroidism, nephrotic syndrome, hepatitis) hypercholesterolemia. Decreased cholesterol is associated with hyperthyroidism, malabsorption, liver disease (many causes), and abetalipoproteinemia.
Triglycerides	Elevations associated with hyperlipidemia (Type I).
High-density lipoprotein (HDL)	Elevation of HDL is associated with a decreased risk of heart disease.
Apolipoprotein A1 (Apo A1)-protein is associated with HDL	Elevation of Apo A1 is associated with a decreased risk of heart disease.
Apolipoprotein B (Apo B)-protein is associated with LDL	Elevation of Apo B is associated with increased risk of heart disease.
Antibodies to Human Immunodeficiency Virus (HIV)	Presence of HIV antibodies presumes infection with HIV and risk of developing acquired immunodeficiency syndrome (AIDS).
T-cell-lymphocyte typing	Suppression of T cells, a sign of immunodeficiency, is associated with several conditions: e.g., AIDS, CMV, mononucleosis, and autoimmune disorders such as systemic lupus erythematosus.
Urine tests	
Protein	Protein in urine is associated with kidney disease.
Glucose	Diabetes Mellitus.
RBCs	Kidney disease, bladder injury.
Casts	Kidney disease.
WBCs	Kidney disease, infection of urinary tract, bladder, kidney.
Tests for prescription medications (e.g., diuretics, beta-blockers, hypoglycemic agents)	Presence of prescription medication in urine is evidence that the patient is being treated for related conditions—e.g., hypertension, heart disease, hypoglycemia—and may indicate level of patient compliance with treatment.
Tests for drugs of abuse (i.e., nicotine, cocaine, other drugs of abuse)	Presence of drug in urine is evidence of drug use (but not impairment).

SOURCES: H.C. Sox, Jr. (ed.), *Common Diagnostic Tests: Use and Interpretation*, (Philadelphia, PA: American College of Physicians, 1987); and C. Pinckney, and E.R. Pinckney, *The Encyclopedia of Medical Tests* (New York, NY: Facts on File, Inc., 1982).

lipid parts of lipoprotein particles (called "oncolipids") found in the plasma of patients with cancer as compared to those without cancer. The differences can be detected using magnetic reso-

nance imaging (MRI). While the test has been shown to successfully distinguish those with some types of cancer from healthy individuals and from those with illnesses other than cancer, there are

two significant sources of false positive results—pregnant women and men with noncancerous prostatic hyperplasia. In addition, individuals who have been successfully treated for cancer continue to test positive. Although currently expensive to administer, the test could be automated and used for screening in the future.

Current methods to identify those susceptible to heart disease rely on tests for symptoms of disease, such as the EKG, or on an analysis of known heart disease risk factors. The three principal predictors of coronary heart disease (CHD), other than age and sex, are hypertension, elevated levels of cholesterol, and cigarette smoking. The risk of developing CHD can be determined by evaluating these factors (and other risk factors, such as diabetes) singly or in combination. For example, the relative risk of developing CHD within 18 years for a 35-year-old male with only high cholesterol, compared to a similar male with normal cholesterol, is 3.9. The relative risk increases to 23.2 when both cholesterol and blood pressure are elevated. Generally, smokers have more than twice the risk for a heart attack than nonsmokers.

Cholesterol screening is being actively promoted by heart disease experts. These efforts have been somewhat hampered by a lack of uniform laboratory quality in the conduct of cholesterol measurement. Measurements of cholesterol, lipoproteins (e.g., high density lipoprotein or HDL, and low density lipoprotein or LDL), and the protein components of lipoproteins (apolipoproteins) are used in the evaluation of CHD risk. Levels of specific apolipoproteins are the most useful in distinguishing healthy individuals from those with CHD. Apolipoprotein tests can be conducted using automated instrumentation and are currently performed by commercial insurers.

As in the case of predictors for cancer, with available testing methods there will be many who will develop heart disease among those predicted to be at low risk, and many at high risk will remain disease-free. Therefore, although the presence of known risk factors raises the relative risk, the absolute risk remains low.

The prevalence of alcohol abuse or dependence is estimated to be between 8 and 10 percent among men and between 1 and 2 percent among women.

The health consequences of alcohol abuse are considerable, and the biochemical profiles currently used by commercial insurers are used to detect the effects of alcohol abuse (e.g., liver disease). Structured questionnaires and laboratory indicators are available to help identify individuals with drinking problems. Evaluations of these screening methods have shown that structured questionnaires are more effective than most laboratory tests. Preliminary research on a biologic marker for alcoholism shows promise (i.e., inhibition of the enzyme, monoamine oxidase, by ethanol and stimulation of the platelet enzyme, adenylylate cyclase). In one study, this marker was used to correctly categorize 75 percent of alcoholics and 73 percent of nonalcoholics. Abnormalities were detected in alcoholics who had abstained from alcohol consumption, suggesting that the test may be a measure of the underlying basis of alcoholism. Further research will be necessary to clarify the utility of this marker.

Methods of Interest for Future Testing

Advances in molecular genetics have led to the development of a number of new diagnostic and predictive tests. While several recombinant DNA-based diagnostic tests are now being marketed in the infectious disease area, a larger market may be realized when tests for common disorders with a genetic component are developed. Evidence is mounting that specific genes may predispose individuals to some forms of diabetes, heart disease, cancer, and mental illness. When these genes or genetic markers for these conditions are identified, predictive tests for these and other disorders may become available. Because genes are present in all body cells, tests can be applied using easily accessible tissues, such as blood, or in the case of prenatal diagnosis, through examination of fetal cells obtained through techniques such as amniocentesis. Thus, tests may be administered at any time prior to the onset of the disease and afford the possibility of therapeutic intervention to prevent the disease.

Several DNA-based tests for relatively rare genetic conditions are already available, but they rely on relatively sophisticated techniques, are difficult to interpret, and therefore are available only

through a few specialized laboratories. The limitations of these tests pose considerable obstacles to their adoption by insurers.

There are two basic approaches to DNA-based testing for genetic disorders. The "linkage method" is being used to offer information to individuals within families in which certain genetic diseases have occurred. Genetic linkage tests are limited, because the exact location of the harmful gene is not known. Instead, the inheritance of gene markers (called "restriction fragment length polymorphisms" or RFLPs) is studied within families. For example, linkage analysis can be applied to Huntington's disease, an inherited disorder of the nervous system. These analyses require the cooperation of many family members (often including more than one generation) and are therefore not widely applicable. Even when the appropriate family members are available and the diagnosis of the genetic condition is well established, linkage tests may not be informative. Not all families have markers that can distinguish affected from non-affected individuals. Furthermore, since gene markers associated with the abnormal gene are examined and not necessarily the abnormal gene itself, erroneous conclusions are possible; for example, when genetic recombinations occur between the disease-causing gene and the marker.

When a disease-causing gene has been identified, direct tests have sometimes been developed that avoid many of the problems associated with linkage analyses. As these tests do not have to rely on the analysis of multiple family members, they may be amenable to population-wide screening. However, there are few conditions for which direct tests are currently available; and with the exception of sickle cell anemia, these conditions rarely occur. As more genes are identified that are associated with common disorders and as testing is simplified, genetic tests will be commercially developed. Until recently, one limitation on the use of genetic tests was the limited amount of DNA that was available for study, especially when analyzing prenatal specimens. Methods have now been developed in which enzymes are used to multiply the DNA sequences as much as 200,000 fold. These advances have simplified and accelerated the testing process and will allow more laboratories to conduct DNA-based genetic testing.

As of the beginning of 1988, there were no FDA-approved recombinant DNA tests for human genetic conditions. A limited number of these tests are available, however, through university genetic-counseling programs or through a few commercial laboratories.

Will insurance companies use genetic tests as part of their underwriting process? Genetic tests in their present state are impractical to administer, require considerable technical skills, may require analyses of multiple family members, are expensive to perform, and are currently available for only a small number of relatively rare diseases. Thus, it appears that in the near future, they will not be directly used in the insurance underwriting process. However, as genetic tests become increasingly available and used by clinicians, results from these tests will become part of the medical records of their patients. Applicants therefore will have to acknowledge their existence when filling out the medical history questionnaires, or insurers will become aware of these tests through attending physician's statements or copies of the applicant's medical records. Thus, insurers will occasionally have to factor these test results into their underwriting decisions. If tests are simplified and are shown to be predictive, they will in some cases be adopted by insurers.

One additional area of medical testing that could influence insurers' use of specific tests is the expected development of more self-testing for the home diagnostic products market. Insurers are always concerned over the problem of "adverse selection;" that is, applicants having knowledge of their medical conditions that is not made available to insurers, who then unknowingly approve these applications on the basis of incorrect risk assessments. (This has been of concern to insurers in those States where they have been prohibited from using the AIDS antibody test.)

There are now approximately 60 do-it-yourself kits available for a variety of conditions, ranging from pregnancy and ovulation to blood in the feces (an indicator of colon cancer). The largest home-testing market so far has been for therapeutic monitoring, such as monitoring by diabetics

of their urine and blood sugar levels. There are currently few home diagnostic tests that prospective insurance applicants could use to determine

whether they should obtain insurance in anticipation of having to seek medical care, but this is an area of obvious ongoing interest to insurers.

CONCLUSIONS, ISSUES, AND OPTIONS

Prospects for Increased Use of Medical Tests by Health Insurers and Employers

Truly new methods for detecting incipient or latent disease and even for predicting disease in healthy persons are being rapidly developed, particularly through recombinant DNA technology. Yet, many technological obstacles need to be overcome before their routine use and widescale applicability progress beyond hope into reality.

Even when these technologies become available, they may not be of practical use for insurers and employers for a number of reasons. First, there may not be a clear cause-and-effect relationship between abnormal findings on any single test and a specific disease, or a significant probability that a positive test would be predictive of developing the disease in the future. Current indicators of predispositions to disease seldom consist of a single factor but instead involve multiple factors whose interrelationships are still not well understood.

Second, tests will probably consist of two types: 1) less specific tests that identify a large number of persons with propensities to develop the index disease, and 2) more specific tests that can identify a subset of susceptible persons who will most likely develop a particular manifestation of the index disease. For example, tests may become available to identify persons who have a higher probability than average to develop cancer, or cardiovascular disease. Simultaneously, more specific tests may be found for identifying persons with a high probability of developing a specific type of cancer, or cardiovascular disease. In the first instance, insurers (and employers) will have to decide whether it is worth it to use a relatively nonspecific test that will be positive in large numbers of people, many (if not most) of whom will never develop the disease. In the second instance,

many people would have to be tested in order to find the relative few with a high probability of developing disease. In either case, insurers (and employers) might find such testing not worth the effort when compared to how they currently deal with the probability that a certain number of their applicants (or employees) will develop these diseases. In other words, insurers already expect that some applicants whom they presently insure will develop these diseases, account for these diseases in their actuarial estimates when determining conditions of insurability and setting premium rates, and therefore might decide it not worth the added costs of testing for the amount of incremental information gained.

Third, while DNA technology holds promise in furthering predictive testing for common chronic diseases, despite rapid progress, it may still be years before such tests become simplified to the point that they can be used to screen large numbers of people in a cost-effective manner.

Fourth, from the viewpoint of clinical medicine, efforts in these areas are not merely directed at identifying persons with high probability (or certainty) of developing a particular disease. The ultimate aim is to find a treatment or cure, or even to prevent the disease. In the long run, many (or at least some) persons at risk for developing disease may avoid or have their illnesses reduced. This is especially true for genetic tests for common disorders where an interaction between environmental and genetic factors contributes to disease expression. Thus, persons currently at risk may eventually be more, not less, insurable.

While insurers might not find it cost-effective to use these tests themselves in screening prospective clients, if such tests are available to the medical community, insurers will still have to take these tests into account when making decisions on whether to insure an applicant, and if so, the

terms under which that insurance will be issued. This will occur in two ways, both of which are already routinely used in evaluating insurance applicants. First, questions on such testing can be incorporated into the medical and family history questionnaire. Second, the use of such tests by the applicant's physician may be revealed when an attending physician's statement is requested or the applicant's medical record is reviewed.

Thus, not surprisingly, *the future impact of diagnostic and predictive medical tests on an applicant's insurability and on insurers' use of these tests will depend primarily on the infusion of these future tests into medical practice and not depend as much on the direct use of these tests by insurers in the underwriting process.* The regulatory implications are therefore quite different if insurers' knowledge of test results comes from the applicant's medical history and information provided by the applicant's physician, rather than from subjecting applicants directly to specific testing.

Will these tests have a significant impact on private insurers' willingness to continue to insure persons whose risks of developing disease can be predicted with fair certainty? Insurers are in the business of providing insurance, and they will continue to provide insurance to as many applicants as affordable. Thus, the impact on future private insurance availability might be limited; *but even such limited impacts might have major consequences for access to health care through private financing channels and the related impact on public health care expenditures, if private financing is reduced, with a concomitant increase in need for publicly financed health care.* Refinements in current methods of assessing risk that these future tests will provide will probably improve decisionmaking in current private health insurance practices. Certain risks currently declined or rated as substandard may in fact be insurable or upgraded to standard risks. The greater impact, however, is likely to occur in the following areas: declining to provide insurance to those at very high risk, charging higher premiums for higher-risk applicants, and issuing policies with certain diseases excluded from coverage. *These practices will aggravate what are already well-recognized shortcomings in our nation's health care system: 1) the problem of the uninsured and*

underinsured, and 2) inadequate catastrophic and long-term health care coverage.

Employers are already engaging in practices to decrease their health care expenditures, such as self-insurance, increasing cost-sharing by their employees through larger deductible and co-insurance requirements, placing limits on the amount that will be expended on individual employees, controlling which providers can provide health care to their employees, or even ceasing or refusing to provide health care benefits to their employees.

Employers may be more interested in using direct methods to control their employee health care costs than in using medical testing as a preemptive means to control expenditures for their employees' health care. While some employers may be incorporating testing into health promotion programs, when employers are concerned over the health of their employees, that concern is primarily related to the impact of poor health on work productivity and the effect on other employees, not on employee health care costs. The focus of employers in testing is presently directed at drug abuse, and while health is a related concern, the primary impetus among employers to adopt drug testing is concern over poor performance, not poor health. Even AIDS antibody testing—when considered by employers for reasons other than uncertainty and fear—seems motivated more by the impact of AIDS on employee morale and customer perceptions than on the treatment costs of AIDS.

Will employers find predictive medical testing more attractive in the future? If they do so, whether their explicit motives include concern over employee health care expenditures would be beside the point, if such screening of applicants and employees nevertheless had the effect of shutting out many people from access to health care through employment-based health care plans.

AIDS: a Unique Situation or a Paradigm for Future Actions?

What actions insurers and employers might take as new diagnostic and predictive medical tests become available are speculations. In contrast, ac-

curate tests for identifying persons infected with the AIDS virus are already available, some decisions on their use have already been made, and other uses are under intense debate.

State legislatures have been most active in taking action on the use of tests to identify persons infected with the AIDS virus, and some of these laws have been directed at insurance and employment testing. The laws, however, have been quite variable. States such as Maine have prohibited insurers from inquiring whether the applicant has previously had an AIDS antibody test performed, but do not prohibit insurers from requesting such tests themselves. Wisconsin prohibited the use of tests for infections with the AIDS virus by insurers and employers but stipulated that tests that were found by the State epidemiologist to be accurate and reliable could be used by insurers. The State epidemiologist subsequently issued such a finding, so insurers—but not employers—can now test for AIDS antibodies in Wisconsin. The District of Columbia prohibited the use of AIDS testing by insurers but not by employers. New York attempted to prohibit use of the AIDS antibody test by insurers but has been denied by the courts. California prohibited the use of the AIDS antibody test by insurers and employers but did not prohibit other types of tests that might be used to indicate signs of AIDS. Commercial insurers in California therefore have been using a test that indicates impaired immune function—the T-cell test—to determine insurability of individual health insurance applicants. Anecdotal reports have since surfaced of applicants offering to show proof of negative testing results for AIDS antibodies when they have been refused insurance on the basis of an abnormal T-cell test, but insurers have declined to reconsider the application, citing the State prohibition in using the antibody test in determining insurability.

Insurers are concerned over prohibitions and limitations on inquiring about prior testing or conducting tests for infections with the AIDS virus because of the problem of adverse selection; that is, insuring persons already infected who apply for health insurance because of their known high probability of developing frank disease.

Are the approaches to insurance and AIDS that have been taken by some of the States unique?

Prohibitions on refusing insurance for specific diseases or handicaps—and the complementary policy of requiring certain types of benefits to be provided—do have precedents. Some States have taken the position that persons with predispositions to some types of diseases or with some types of impairment, such as DES exposure (a drug that was used to prevent miscarriages but which subsequently was found to increase the risk of cervical cancer in female offspring of these women) or blindness, cannot be declined or charged higher premiums. And some types of benefits, such as treatment for alcoholism or drug addiction, are mandated by some States. *Issues concerning AIDS and private health insurance, therefore, may be more a matter of degree than novelty when compared to how other illnesses and benefits have been addressed in the past.*

Yet, there are novel aspects to the issue of insurance coverage for AIDS. It is a new disease, and its major routes of infection—sexual practices and intravenous drug use—predominantly affect young people. Employed young adults are the low-risk groups that subsidize the health care of other groups through their lesser need and use of health care services. Furthermore, by affecting young adults, the costs of caring for AIDS patients, while small relative to total health care costs, represent unanticipated additional costs. Furthermore, projections of the number of HIV-infected persons and AIDS cases even over the next decade are alarming. New treatments for AIDS are likely to increase health care costs for AIDS by prolonging the life of afflicted patients with expensive new drugs. These patients will probably continue to experience significant morbidity, thereby expanding their current needs for health and related support services.

Adding to the complexity of insurance coverage for HIV-infected persons is the knowledge that, at least for the next decade, the primary weapon against AIDS will not be found in the laboratory. The primary means to prevent further spread of HIV infections is, and will continue to be, education. The essential point of these educational messages is that infections with the AIDS virus are preventable, and that most persons can prevent infection through changes in, or avoidance of, known high-risk behaviors. (There are,

of course, significant exceptions to the notion that risk is avoidable through individual behavior. These exceptions have included blood recipients, hemophiliacs, infants born to infected mothers, spouses of infected persons, and health care workers who have been accidentally stuck with contaminated needles.)

If an individual's destiny insofar as AIDS is concerned rests in his or her own behavior, why should exceptions to the health insurance risk assessment process be made for HIV-infected persons? A partial answer to this question is that insurance availability isn't the real issue, but that confidentiality of HIV antibody testing and other information that might identify an individual to be at risk for AIDS is the paramount issue, because of the profound discrimination and ostracism currently associated with AIDS. However, confidentiality is not the only issue. Clearly, persons at risk for becoming infected or who are already infected with the AIDS virus not only want their confidentiality maintained, they also want affordable access to health care.

A fundamental issue is whether HIV-infected persons and AIDS patients have a special claim on health care resources over persons afflicted with other catastrophic illnesses. One criticism of a special claim for AIDS is that such an approach is in direct conflict with the message that HIV infections are preventable through voluntary behavior, especially when those behaviors are, in the main, extremely sensitive and socially divisive subjects; such as, sexual practices and intravenous drug use. Even were these practices not involved, however, equity and cost considerations would be raised. *Since the extension of Medicare coverage in 1972 to include a specific disease, end stage renal disease (ESRD), and the attendant high costs of the ESRD program, costs alone have been an effective barrier against a disease-by-disease approach to health care for catastrophic illnesses.*

Concerns over the accuracy and reliability of HIV antibody testing raise related and quite similar questions. The technical issues relating to AIDS antibody testing are important though not unique. They are highly visible manifestations of similar concerns that apply to all medical testing, for there are inherent limitations on the accuracy and reliability of all clinical laboratory tests.

First, the abnormality or change in body function that is associated with the suspected disease or condition and which a particular test is designed to detect may not be present, even though the disease or condition is present. For example, in the test to detect occult blood in feces, a colon polyp or colon cancer may be present in the person tested, but there may not be blood in the feces at the time of testing. In HIV infections, an HIV antibody test may be performed during the early stages of infection when no or very small amounts of antibody are present.

Second, every test has its technical limitations; for example, there will always be some specimens in which the abnormality is in such low concentrations that the test either cannot detect the abnormality or cannot consistently and reliably detect it. Many tests have a "cutoff" point below which the results will be interpreted as negative. In general, when the cutoff point is lowered so that more test specimens will be interpreted as positive, more specimens without the abnormality will also be erroneously identified as being positive. In other words, when a test is made more "sensitive" so that fewer positive specimens will be missed ("false negatives") it will also be less "specific" and identify more negative specimens as positive ("false positives"). To illustrate, in AIDS antibody testing by blood banks, the ELISA screening test has been deliberately calibrated to have a very high sensitivity so that as many positive blood donations can be identified as possible. But this also means that most of the ELISA-positive blood specimens are not really positive, so testing of these positive specimens by a different method—the Western blot—is necessary. In 1987, American Red Cross rates for positive ELISA specimens were approximately 10 in 10,000. Upon Western blot testing, 8 of 10 specimens were negative, 1 was positive, and 1 was indeterminate. The "indeterminate" result points out that the Western blot test also has its limitations, with the indeterminate specimen probably representing early infection with the AIDS virus in most but not all cases. (Blood banks do not use any of the ELISA positive specimens, even when negative with Western blot testing.)

Third, it is axiomatic that the accuracy and reliability of tests when performed under every-

ACCEPTABLE UNACCEPTABLE

gp160—
gp120—p64—
p55—
p53—

gp41-p45<

p31—

p24—

p15—

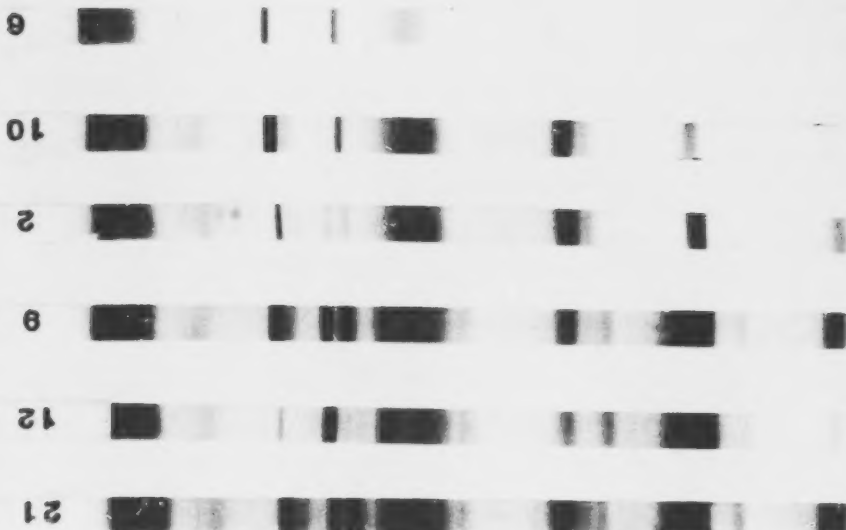


Photo credits: Department of Virus Diseases, Retrovirus Section,
Walter Reed Army Institute of Research

(Above) Western blot preparation for HIV antibodies.

(Right) Examples of six strongly positive reactions.

day rather than ideal conditions will fall below their technically achievable levels. Moreover, there will be great variability among individual laboratories performing these tests. Variable accuracy occurs even when laboratories are tested and know they are being tested ("open testing"), and not surprisingly, laboratory performance will be worse when they do not know they are being tested ("blind testing"). In other words, there is a technical level of accuracy and reliability that is potentially achievable with each test, but most laboratories will not be able to achieve this potential even when they know they are being tested, and few laboratories will perform at optimal levels in their everyday practices.

Finally, even when the tests are performed with the same degree of accuracy across different populations, the probability that a positive test result will be correct will still decrease as the rate in which the abnormality is present in the tested population decreases. This is a simple mathematical fact. Suppose the sequence of tests—the ELISA screening test and the Western blot confirmatory test—will identify everyone with HIV antibodies in their blood and falsely identify only 1 in 100,000 persons as having HIV antibodies when they do not. In a population in which 10 percent had HIV antibodies, 10,000 of 100,000 persons tested would be correctly identified as positive. Among the remaining 90,000 antibody-negative persons, only 1 would be incorrectly identified as being HIV-antibody positive. Of the 10,001 positive tests, therefore, 99.99 percent of positive results would be correct. This "predictive value" of a positive test changes dramatically when a population with only a few HIV-antibody persons is tested. If only 10 in 100,000 were antibody positive, again, only 1 in the 99,990 HIV-antibody negative persons would test positive. However, in this case, there would only be a total of 11 positive results, and 10 of 11, or only 90.91 percent, would be correct. (Note that the predictive values would be even lower if the ability to detect all positive specimens was not assumed to be 100 percent.)

Tests with false positive rates of only 1 in 100,000 are extremely rare, if not unheard of outside of HIV antibody-testing. Blood bank testing and the Department of Defense's HIV-antibody

testing program (and probably HORL, Inc., the major lab used by the insurance industry) may perform at this high level because of stringent quality controls over the laboratories conducting their tests, but it is not unreasonable to question whether the average lab conducting HIV-antibody testing can reach this level of accuracy. There is in fact evidence that the average lab not only has a much higher rate of false positives, but is also missing a number of HIV-antibody positive blood specimens.

HIV-antibody testing has received much scrutiny because of the controversies surrounding use of the test in underwriting life and health insurance for individuals and more importantly, in attempts to make testing mandatory among segments of the United States' population. Mandatory testing has been implemented in some areas, such as in the military, among immigrants, and for premarital testing in Illinois and Louisiana (and Texas, but the law there requires that infections in the State must reach a rate of 0.83 percent before premarital testing is initiated). However, the underlying technical issues concerning test accuracy, especially as actually conducted by laboratories, are common to all diagnostic and predictive testing. Periodically, questions have been raised over specific medical tests. For example, laboratory performance in Pap testing for cervical and uterine cancer is currently under scrutiny, as is the accuracy and reliability of urine drug testing. Thus, the issues concerning HIV-antibody testing accuracy and reliability are common to all types of medical testing, although HIV-antibody testing deserves special scrutiny because of the societal consequences of being infected with the AIDS virus.

Options Addressing the Use of Medical Tests

A wide range of initiatives has been and is being used to improve the accuracy and reliability of medical testing.

First, laboratories have been provided "proficiency testing" services to assist them in maintaining and improving the accuracy of their performance. In proficiency testing, participating laboratories are sent prepared specimens (usually on a

quarterly basis), which they then test and report back their findings. For example, the College of American Pathologists (CAP) has an extensive proficiency testing program in the various types of tests used in clinical medicine, as well as in AIDS antibody testing and drug testing (e.g., urine testing for cocaine, marijuana, opiates, etc.). In these programs, laboratories voluntarily participate for an annual fee and know when they are being tested—they receive test specimens at expected times and report their results back directly to the testing organizations. This is why these programs are called "open" proficiency testing.

In the 1970s, the Federal government, through the Centers for Disease Control (CDC), provided open proficiency testing services in a number of clinical testing areas. Most of these activities were phased out in the 1980s. However, because of the AIDS epidemic, CDC has now begun a proficiency testing program for AIDS antibody testing.

Second, the quality of medical testing can also be maintained by setting standards for laboratory personnel and testing procedures. Two methods are available for setting standards for laboratory personnel and performance: 1) set standards as part of direct licensing of laboratories, or 2) use standards as a necessary condition in order for labs to be reimbursed for services they perform.

Direct laboratory licensing has traditionally been in the purview of the States, but there is a great degree of variation in licensing. Few States regulate laboratory performance to any significant degree, and even within a State, monitoring can vary tremendously among the different types of tests—for example, clinical medicine testing versus drug screening testing. One variation in this approach is not "licensing" in the strict sense, but could be considered for specific types of testing. For example, New York prohibits commercial labs from performing AIDS antibody tests and specifies the types of labs that are allowed to perform these tests. Thus, designating the labs that are allowed to perform testing is a variation on standard setting.

In the Medicare program, laboratories must meet specified personnel and performance standards as a condition of participation (i.e., if they expect to be reimbursed for their services). For

example, laboratory directors must meet certain educational/professional qualifications, and labs must participate and maintain a certain minimum score in specified proficiency testing programs (e.g., those of CAP).

Third, laboratory performance can be directly monitored. On-site inspections of labs are conducted by a few States whose laws and resources permit such activities, and similar inspections are periodically conducted by the Federal government on labs participating in Medicare. Criticisms over the frequency of these inspections and the number and types of labs subject to such inspections, however, are longstanding issues at both the State and Federal levels. Moreover, on-site inspections do not directly measure lab testing performance.

Participation in proficiency testing of the types offered by CAP is a method of monitoring laboratory performance, but this type of "open proficiency" monitoring only reflects at what level a lab is capable of performing. Open testing is not reflective of a lab's performance in everyday testing, and that level of performance can only be evaluated if the lab does not know it is being tested. Thus, "blind" testing has been instituted in some areas in which test samples have been inserted along with specimens received by the lab from one or more of its actual customers. In blind testing, labs know they are being tested, but do not know when they are being tested and which specimens are the test specimens. For example, in the Department of Defense's (DOD) extensive AIDS antibody testing program, DOD uses a monthly blind testing program to evaluate its contractor lab's performance (if the lab fails a certain amount of these tests, it does not get paid for that month). A similar program has been developed by the National Institute on Drug Abuse (NIDA) to monitor labs performing tests for the expanding urine drug testing program for selected Federal employees and contractors.

In blind testing of labs, implementing and maintaining the program are much more difficult than in open testing. In open testing, specimens can be sent directly to the lab, which then reports its results to the testing organization. In blind testing, arrangements must be made with actual customers of each lab; and the lab, because it cannot dis-

tinguish between real and test specimens, would be reporting the results to each customer. Thus, the administrative costs of a blind program would be much higher than in open testing.

If blind testing is used, a decision has to be made whether the Federal government would administer the program directly or by contracting it out, or whether arrangements would be made with existing, voluntary proficiency testing programs such as CAP to administer the program.

Finally, it must be remembered that it is the States, not the Federal government, that are most involved in regulating the quality of medical testing. Figures 1-2 to 1-5 summarize the extent of State regulation of laboratories that perform medical testing.

Congressional interest in the accuracy of laboratory testing has increased as a result of expanding urine drug testing programs, the continuing controversies over AIDS antibody testing, and more recently, concerns over the accuracy of medical testing in general. Several committees in both the House of Representatives and the Senate have held hearings on these issues (e.g., Committees on Energy and Commerce, Small Business, Post Office and Civil Service, and Government Operations in the House of Representatives; and Committees on Labor and Human Resources, Judiciary, and Governmental Affairs in the Senate). Thus, in addition to monitoring and proficiency testing of laboratories under contract to DOD to perform AIDS antibody testing and a similar program under NIDA for laboratories performing urine drug testing on designated Federal employees and contract personnel, current congressional scrutiny is focused on the laboratories performing medical testing in general, and especially those who participate in the Medicare program.

More recently, there also have been attempts to determine the appropriateness of using testing in specific circumstances, and to determine when the use of certain tests are justifiable. These approaches in fact have been used by some States. Thus, there are two options in addition to the more traditional means of maintaining and improving the accuracy and reliability of medical testing through standard setting and proficiency testing.

Option 1: Allow use of a particular test only under specifically defined circumstances; for example, as some States have done for HIV-antibody testing for insurance and/or employment and for employment-based urine drug testing.

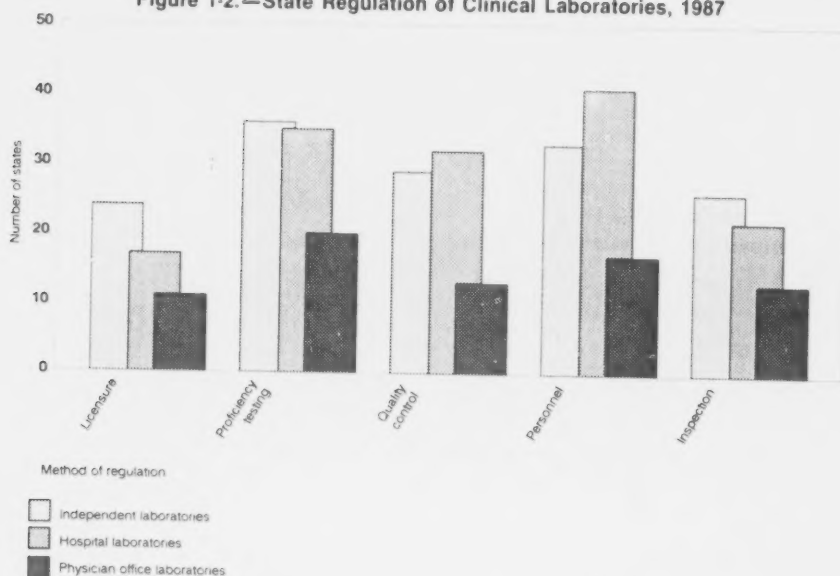
This option would be applicable to specific tests and specific situations. An example is defining the circumstances in which drug testing of employees will be allowed. For example, in 1987, seven States passed such laws; six of these States limited drug testing to circumstances in which probable cause or reasonable suspicion existed. The other prominent example is the numerous variations among the States in defining when and under what circumstances (e.g., insurance underwriting, job applicant and employee testing) AIDS antibody testing is curtailed or prohibited.

While this option is not primarily based on an assessment of a test's accuracy and reliability, such considerations nevertheless are at least implicit in the reasoning. Recall the discussion above on the poorer predictive value (i.e., that a positive test result is truly positive) of a test when applied to populations with lower and lower rates of the index condition. Lower predictive value—and the increasing chances of a false positive identification—is among the reasons why caution is advised in screening low-use populations for drug use and low-risk populations for AIDS antibodies. Cost-effectiveness also becomes a consideration in screening low-use or low-risk populations, because everybody must be screened—and each positive on screening must be confirmed—in order to find the very few persons who are truly positive.

Testing does have the potential of helping those being tested. For example, one rationale for drug testing is to identify users in order to rehabilitate them. Tests could also be used to identify low-risk individuals to "exonerate" those with a positive family history for the disease (e.g., Huntington's disease).

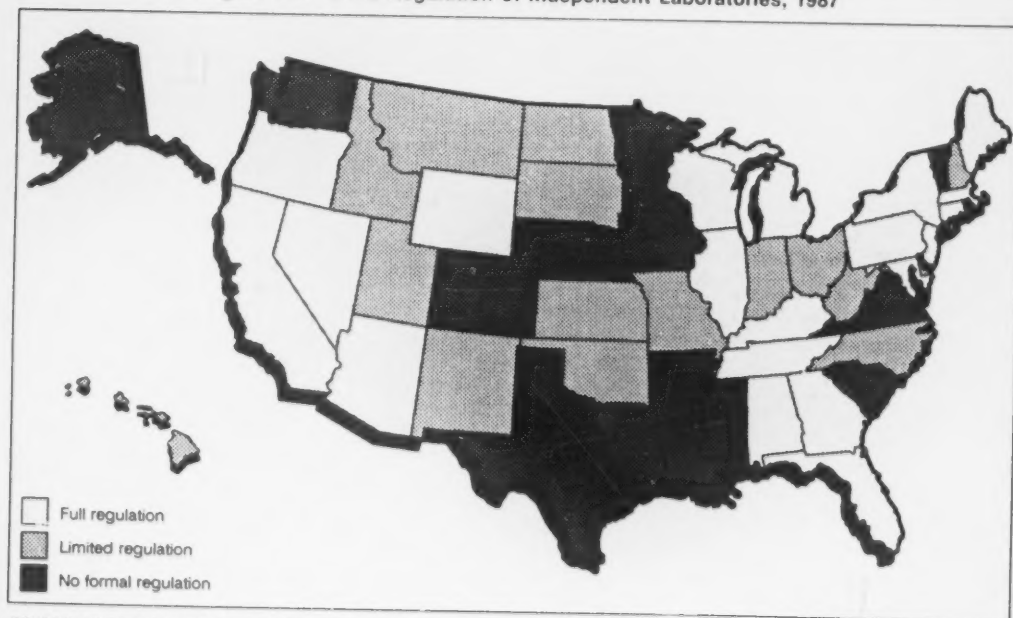
Option 2: Limit the use of tests to tests that have been determined to be sufficiently accurate and reliable in the specific circumstances in which they are to be used.

Figure 1-2.—State Regulation of Clinical Laboratories, 1987



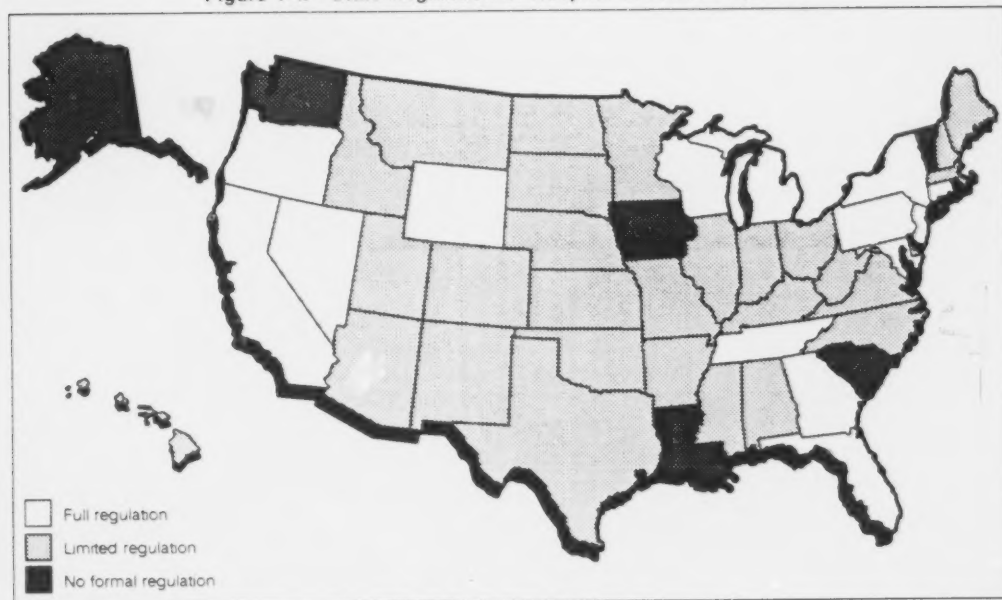
SOURCE: D.P. Baine, Associate Director, Human Resources Division, U.S. General Accounting Office, Washington, DC; information provided to The Honorable Ron Wyden, Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives, Feb. 29, 1988.

Figure 1-3.—State Regulation of Independent Laboratories, 1987



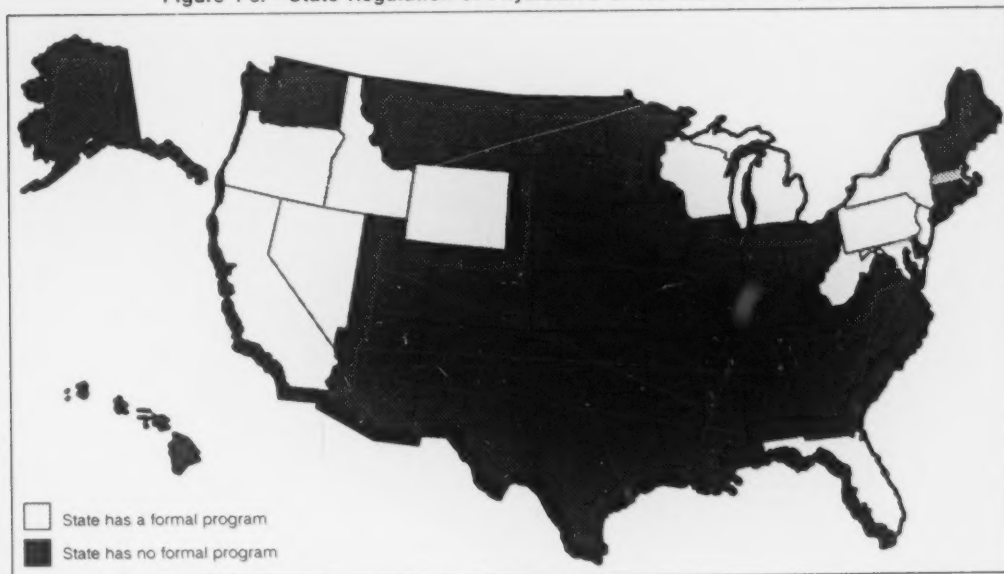
SOURCE: D.P. Baine, Associate Director, Human Resources Division, U.S. General Accounting Office, Washington, DC; information provided to The Honorable Ron Wyden, Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives, Feb. 29, 1988.

Figure 1-4.—State Regulation of Hospital Laboratories, 1987



SOURCE: D.P. Baine, Associate Director, Human Resources Division, U.S. General Accounting Office, Washington, DC; information provided to The Honorable Ron Wyden, Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives, Feb. 29, 1988.

Figure 1-5.—State Regulation of Physician's Office Laboratories, 1987



SOURCE: D.P. Baine, Associate Director, Human Resources Division, U.S. General Accounting Office, Washington, DC; information provided to The Honorable Ron Wyden, Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives, Feb. 29, 1988.

An available measure of a test's accuracy and reliability is licensing for commercial use by the Federal Food and Drug Administration (FDA); that is, FDA makes its licensing decision on a determination of test accuracy and reliability. However, FDA recommendations on when and how FDA-licensed products should be used are not necessarily followed. This is clearly the case in prescription drug use, where physicians often feel that once a drug is approved, they should be the ones to determine the circumstances of their use.

Some States have gone beyond FDA licensing and have expressed quite divergent views on this approach when applied to AIDS antibody testing. The Wisconsin legislature's approach was to require a finding by the State epidemiologist on whether a test was sufficiently accurate and reliable to use for insurance purposes (the State epidemiologist did make such a finding for the AIDS antibody test). In contrast, a proposed New York regulation was based on the conclusion that the presence of AIDS antibodies reflected infection with HIV and did not necessarily mean progression to frank AIDS, and thereby attempted to deny use of the test by insurers (initial court decisions have ruled against this prohibitory regulation). In California use of the AIDS antibody test is prohibited, but not other tests such as the less specific T-cell test.

Criteria that have been informally proposed by one insurer on the conditions that usually must be met before a medical test will be adopted by insurers are as follows:

- The test must supply information in addition to information otherwise available from other sources (e.g., from the medical history questionnaire).
- The disease tested for must have serious morbidity and/or mortality implications.
- The disease must be common enough to ensure that the test is predictive and that costs of testing can be justified.
- The test must be predictive of disease (or absence of disease) and reliable.
- The test must be understood, accepted, and used by the medical profession.
- Laboratories must be able to readily perform the test.
- The test must be affordable and able to provide results quickly.
- The test must be risk-free.

Criteria such as these could be adopted by the National Association of Insurance Commissioners (NAIC) and issued as guidelines.

Options on Strategies for Maintaining and Improving Access to Health Care

In the foregoing discussion on options to improve lab accuracy and reliability, each option can apply to lab testing of all types, or to specific types of testing (e.g., clinical medicine testing, AIDS antibody testing, drug testing) as circumstances and priorities dictate. An analogous situation exists in the area of financing of and access to health care. In developing strategies for maintaining and improving access to health care, one prominent issue is whether financing for AIDS care deserves a special, categorical approach or whether it has no special claim on the use of health care resources. However one comes out on these opposing policies, in general, the financing issues are similar for AIDS patients and patients suffering from other diseases. Thus, the policy choices are essentially the same for categorical and generic approaches, and how policymakers address AIDS versus other illnesses will depend on particular circumstances and priorities.

While the broader policy approaches are relatively easy to identify, the underlying issues are complex; and the specific policies that might be implemented are not only controversial, but each specific policy is also wrapped up in its own set of complexities and controversies.

Policymakers are well aware of the broad as well as the specific policy choices, and sustained efforts have been going on at Federal and State levels for at least the past 20 years. The financing needs of AIDS patients have only heightened the intensity of these efforts, but AIDS is not alone in contributing to the sense of urgency. Similar issues have arisen for patients in need of transplants or artificial organs and for technology-dependent children. Furthermore, the acute care needs of persons suffering from catastrophic illnesses is just the front side of the access and fi-

nance problem. Shortcomings in long-term care have long been recognized, which have gained added prominence by recent attention to Alzheimer's disease. The care of AIDS patients raises all of these issues.

Issues concerning health care access and financing include:

- the uninsured and underinsured,
- coverage for catastrophic illnesses,
- discontinuities or gaps in coverage (e.g., between acute and disability care),
- coverage and availability of long-term care, and
- the apportioning of financial responsibilities between private and public sector programs.

Given the breadth and complexity of these issues, it is clear that a list of options addressing these issues would be no less than an attempt to address every aspect of the United States' health delivery system. For example, there is wide agreement that long-term care needs are great, but these services have often not been developed and are often nonexistent even when financing is available. Thus, certain crucial elements of our health care delivery system are lacking or inadequate. Making financing available for these elements would assist in developing the necessary resources. Addressing areas in which the underlying services are in short supply or not available to begin with, however, makes for an extremely more difficult task than in addressing how available services might be made more accessible.

This report has a more narrow focus than the large issue of how health care can best be made available in the United States. The report addresses how medical and health-related laboratory tests are used and may be used in deciding whether specific individuals will be able to obtain health insurance, whether from insurance companies or through self-insured employers. Health insurance availability is currently high on Congress's agenda through such mechanisms as extensions of employment-based health insurance for ex-employees and efforts to require non-contributing employers to provide health benefits to their employees. While these efforts address the issue of inadequate or unavailable health insurance, they do not directly bear on the issue of

medical testing. For example, a small firm may not provide health benefits to its employees, some of whom will have purchased health insurance policies individually. Or a small firm might have purchased health insurance for its employees, each of whom might have been individually evaluated by the health insurer (recall that small groups are often underwritten in the same manner as individuals). In the first case, requiring small firms to provide health insurance for their employees would obviate the need of individual employees to seek health insurance on their own. It would also ensure that all employees would be covered, not just those conscientious enough to purchase insurance. In the second case, there would be no difference if insurance coverage were mandated (except for the possibility of a change in the benefits covered by the insurance), because the employer already offered it.

If we limit the analysis to those areas most affected by medical screening practices by health insurers and employers, and further limit the analysis to those areas of health care uniquely affected by these practices, then the principal issues involve the medically uninsurable population and coverage for catastrophic illnesses. Those who fall in these categories will have severe deficiencies in access to long-term care as well as gaps between acute and long-term care coverage, but so will those currently with health insurance.

Finally, one of the issues leading to the congressional request for this report was the possible impact on public health care expenditures if private insurers declined to underwrite large numbers of applicants based on improved knowledge of latent and future illnesses. Insurers will in fact want to underwrite applicants as long as they can charge premium rates they consider reasonable. Thus, *the premise underlying the following options is that private insurance mechanisms will continue to be used to the extent possible for employed individuals (and their dependents).*

Option 3: Encourage the development of methods to provide insurance to high-risk individuals and those with catastrophic illnesses.

Insurance pools for high-risk individuals and for catastrophic illnesses are not only undergoing experimentation among many States with both

State and foundation (e.g., the Robert Wood Johnson Foundation) funds, but several States have already established pools, especially for high-risk individuals who are unable to obtain health insurance. Current State high-risk pools have large deductibles, high premiums, stop-loss provisions, and maximum lifetime benefits. Interest in such arrangements is high among many of the remaining States. However, experience with such pools is very limited. Direct costs to participating individuals are very high, yet expected and actual shortfalls between premiums and claims expenses are the rule. These shortfalls are financed either through mandatory contributions by insurers doing business in the State (which can be offset against their premium taxes), or by State general revenues.

Two of the principal issues concerning these emerging pool arrangements are: 1) the proliferation of pools with varying eligibility criteria and benefits, and 2) how shortfalls in revenues are to be covered.

Option 3A: Amend the ERISA legislation so that self-insured groups can be required to help finance State high-risk insurance pools.

Because of the ERISA exemption, self-insured health plans cannot be required to contribute to meet the revenue shortfall in those States with pools funded by mandatory contributions by insurers. Thus, insurers have called for Federal legislation to remove this exemption for self-insurers from ERISA. A limited version of this option is to require that employers pay the premiums of employees who would be eligible to join the State high-risk insurance pool. However, as premiums already fall short of covering the total expenses of these pool arrangements, this approach would increase revenue deficits as the number of participants increase, and such employers may have incentives to terminate insurance for their employees with high medical costs because of the lesser cost of transferring these employees to the State high-risk pool.

Option 3B: Provide or require uniformity in eligibility, cost-sharing, and benefits for State high-risk pools.

Although the provisions for these State pools are similar, there are varying eligibility require-

ments and benefits. On a voluntary basis, the NAIC could develop guidelines; or Federal legislation could specify the terms under which State pools function.

Option 3C: Establish Federal high-risk pools in place of State pools.

Federal legislation could also be considered to require States to establish high-risk and/or catastrophic illness pools, or to establish a Federal program along the lines of the catastrophic insurance proposals that have been periodically considered in the Congress.

Option 4: Use incentives and subsidies to provide (and maintain) private health insurance for the uninsured and persons at high risk or with catastrophic illnesses.

Option 4A: Create larger risk pools for smaller firms.

By creating larger risk pools, premiums can be lowered for small employers who band together and act as a large employer. Multiple Employer Trusts (METs) have not lived up to expectations along this line, but it is not clear why this is the case. Larger risk pools for small firms could also be created through approaches similar to the Federal unemployment insurance tax.

Option 4B: Use public funds to subsidize participation in private insurance arrangements for high-risk individuals rather than transferring such persons to public assistance programs.

Direct costs to public programs, as well as the administrative costs associated with switching from one claims processor (private) to another (public), may make public programs that subsidize all or part of private insurance premiums before these persons' insurance policies lapse more cost effective than leaving such persons to exhaust their resources and eventually become eligible for Medicaid (or Medicare). Another possibility would be to subsidize or share the costs of premium contributions to State high-risk pools for persons who might otherwise become eligible for Medicaid or Medicare.

Option 4C: Provide "gap" insurance through further extensions of employment-based coverage and use of Medicare stop-loss measures for

those persons in danger of losing private insurance.

Little is known about the extent to which persons with private insurance eventually lose coverage because of the duration of their catastrophic illnesses, either through inability to continue paying premiums, exceeding their coverage limits, and/or nonrenewal of their insurance policies. Anecdotes abound of these occurrences among AIDS patients and their eventual eligibility for Supplemental Security Income and Medicaid, and of persons who become medically indigent but not quite eligible for Medicaid and must continue treatment through other public (e.g., county, municipal) and private (e.g., unreimbursed) resources.

Under the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, non-government and nonreligious employers with more than 20 employees must give employees who leave the option of remaining in the employee group for health insurance for up to 18 months, as long as the employee pays the employer and employee shares of the premium, plus no more than another 2 percent of the total premium.

For those with illnesses and disabilities that would make them eligible for Medicare coverage, extension of COBRA could cover the period between loss of private health insurance and enrollment into the Medicare program. As there is a preliminary 6-month waiting period before Medicare's 2-year formal waiting period (to establish permanent disability) begins, thereby resulting in an actual waiting period of 30 months, COBRA benefits could be extended to 30 months. Alternatively, COBRA benefits could be extended to 24 months while concomitantly reducing the formal Medicare waiting period to 18 months. This combination of options, of course, would only be available to persons who could meet current Medicare requirements for total and permanent disability, or who would meet Medicare age eligibility in the interim period.

Option 5: Ease eligibility requirements for Medicare and/or Medicaid.

Option 5A: Reduce the Medicare waiting period and/or change the disability definition.

Changes in the Medicare program have been suggested as a way, for example, of financing the health care of AIDS patients. Suggested changes include reducing or eliminating the waiting period, and/or changing the definition of total and permanent disability, such as through disease-specific categories as is currently the case for end-stage renal disease (ESRD). However, as discussed previously, this approach brings up the issue of a disease-by-disease versus generic approach to the disability provisions of Medicare, and in the case of AIDS, the issue of favoring AIDS patients over persons with other catastrophic illnesses.

Option 5B: Expand Medicaid eligibility by raising eligibility ceilings.

If Medicaid eligibility were expanded to all people below some fraction of the poverty level, it would particularly help the very poor in States that currently have low income eligibility ceilings, as well as IV drug users and homosexual men with AIDS who do not meet current categorical eligibility criteria for Medicaid (e.g., custody of children) but who are below the poverty level.

Option 5C: Allow selected buy-ins into the Medicaid program.

Another use of Medicaid to reduce the pool of uninsured is to allow people who are categorically ineligible for Medicaid but who have incomes below some multiple of the poverty level (e.g., 75 percent or 150 percent of the poverty level) to buy into Medicaid on a sliding-scale fee basis. The extent of the Medicaid premium that is subsidized would determine participation. If only a small fraction of the premium is subsidized, few of the poor would be likely to buy in.

Option 6: Supplement Federal payments or provide special grants to areas and/or institutions highly affected by catastrophic illnesses.

The impact of catastrophic illnesses may fall unevenly on different geographic areas and on different institutions in a geographic area. This has been the pattern with AIDS, and because of the programs of care that have been developed (e.g., San Francisco) or the types of patients that have been affected (e.g., drug abusers in New York City), specific areas and specific institutions within those areas may bear a burden out-of-proportion to

what would be expected if only permanent residents of those areas sought care. Thus, a double burden might be imposed: first, on the patients, for whom financial resources will be less available because of the numbers of similar patients seeking care, and second, on the providers of care, because of the additional resources that are needed to provide the extra care. Many, if not most, of these patients will have exhausted their private resources or will already be supported by public programs.

Supplements could be provided on both individual and institutional bases; that is, through diagnosis-specific supplements in the Medicaid program, and direct grants to institutions—especially public institutions—with disproportionate

shares of catastrophically ill patients. In the current Medicaid waiver program, expenditures cannot exceed levels currently provided for traditional services. Granting of supplemental funds could include—or be used exclusively for—development of alternative sites of care and new types of services and thus be used to augment the current Medicaid waiver program.

These options are summarized in table 1-3. Table 1-4 summarizes State laws and regulations concerning HIV antibody testing by insurers and by employers. Table 1-5 summarizes health insurance legislation before the Congress as of April 1988, concerning coverage for the uninsured and provisions for high-risk individuals (excluding Medicare-specific legislation).

Table 1-3.—Major Issues and Related Options

Use of medical tests	Access to health care
Current situation: Few States regulate laboratory performance to any significant degree. In the Medicare program laboratories must meet specified personnel and performance standards as a condition of participation. Current congressional scrutiny is focused on the performance of laboratory testing in general; i.e., clinical medicine testing, HIV antibody testing, and urine testing for illegal drug use. There have been State actions determining when the use of certain tests are justifiable and the circumstances under which it is appropriate to use certain tests (e.g., HIV antibody tests). OTA options: #1: Allow use of a particular test only under specifically defined circumstances; for example, as some States have done for HIV-antibody testing for insurance and/or employment and for employment-based urine drug testing. #2: Limit the use of tests to those that have been determined to be sufficiently accurate and reliable in the specific circumstances in which they are to be used.	Current issues: Issues concerning health care access and financing include: 1) the uninsured and underinsured, 2) coverage for catastrophic illnesses, 3) discontinuities or gaps in coverage (e.g. between acute and disability care), 4) coverage and availability of long term care, and 5) the apportioning of financial responsibilities between private and public sector programs. In addressing these issues, private health insurance mechanisms will continue to be used to the extent possible for employed individuals and their dependents, and there is great resistance to a disease-specific approach for coverage of catastrophic illnesses. OTA options: #3: Encourage the development of methods to provide insurance to high-risk individuals and those with catastrophic illnesses. #3A: Amend the ERISA legislation so that self-insured groups can be required to help finance State high-risk insurance pools. #3B: Provide or require uniformity in eligibility, cost-sharing, and benefits for State high-risk pools. #3C: Establish Federal high-risk pools in place of State pools. #4: Use incentives and subsidies to provide (and maintain) private health insurance for the uninsured and persons at high risk or with catastrophic illnesses. #4A: Create larger risk pools for smaller firms. #4B: Use public funds to subsidize participation in private insurance arrangements for high-risk individuals rather than transferring such persons to public assistance programs. #4C: Provide "gap" insurance through further extensions of employment-based coverage and use of Medicare stop-loss measures for those persons in danger of losing private insurance.

Table 1-3.—Major Issues and Related Options—Continued

Use of medical tests	Access to health care
	#5: Ease eligibility requirements for Medicare and/or Medicaid. #5A: Reduce the Medicare waiting period and/or change the disability definition. #5B: Expand Medicaid eligibility by raising income eligibility ceilings. #5C: Allow selected buy-ins into the Medicaid program. #6: Supplement Federal payments or provide special grants to areas and/or institutions highly affected by catastrophic illnesses.

SOURCE: Office of Technology Assessment, 1988.

Table 1-4.—State Laws and Regulations Concerning HIV Antibody Testing by Health Insurers (as of April 1988)

Arizona:

Insurance department action—A circular letter contains underwriting guidelines implemented to protect against unfair discrimination. No questions may be asked regarding lifestyle, sexual preference, receipt of blood transfusion, previous AIDS-related tests or exposure. The guidelines prohibit the sale of policies containing a general exclusion for AIDS and AIDS-related claims. Informed consent required.

California:

Legislation—Prohibits using the results of blood tests which detect antibodies for AIDS to determine insurability, including the ELISA and Western Blot. Tests for deficiency of immune status, such as T-cell tests, are not prohibited. Prohibits testing without written consent.

Insurance department action—A regulation prohibits discrimination based on sexual orientation. Insurers may not ask about prior blood tests or results.

Colorado:

Legislation—Prohibits testing for HIV infection without consent of the individual.

Insurance department action—A regulation includes the NAIC guidelines. Testing is permitted if the three-test protocol is followed (ELISA-ELISA-Western blot). Policies cannot exclude or limit coverage for AIDS-related treatment.

Connecticut:

Insurance department action—No questions about AIDS testing may be asked, but insurers are not prohibited from testing.

Delaware:

Insurance department action—A regulation requires written consent in order for an applicant to be tested and outlines the types of questions allowed. The NAIC guidelines have been issued as a bulletin.

District of Columbia:

Legislation—Prohibits insurers from requiring or requesting anyone to reveal if he has taken a test to screen for AIDS antibodies and prohibits insurers from refusing to insure an individual or limiting or changing coverage in any way because he has tested positive on any test to screen for AIDS antibodies. The statute also prohibits using factors such as occupation or sexual orientation to determine insurability. Testing is, however, permitted where the applicant exhibits symptoms of AIDS. Insurers can deny cov-

erage to an applicant with AIDS but not someone with HIV antibodies and no symptoms of the disease. Informed consent required.

Florida:

Legislation—Test results from serologic tests conducted under a declaration by the State Department of Health and Rehabilitation Services are prohibited from being used to determine insurability.

Insurance department action—NAIC guidelines adopted. A regulation requires written consent before any testing procedure. Coverage may not be written containing an exclusion for a specific disease.

Hawaii:

Legislation—Health care providers are forbidden from testing a person for the presence of HIV antibodies without written informed consent. The Unfair Trade Practices Law forbids insurers to refuse to insure someone, or limit his coverage, because he has previously had an HIV test, or because he refuses to release information related to a prior test. The insurer may, however, get permission from the applicant and have a test done in a manner which satisfies the requirement of the commissioner.

Illinois:

Legislation—Any insurance company must have written consent before testing applicants for HIV antibodies. No insurer may discriminate in the availability of insurance on the basis of sexual preference, or apply different rates on the basis of sexual preference unless the rating classification is based on expected claims, costs, and expenses.

Indiana:

Insurance department action—A pending regulation includes the NAIC guidelines; however, testing is permitted if testing requirements and protocol are followed.

Iowa:

Insurance department action—The NAIC guidelines have been adopted; testing is permitted.

Kansas:

Insurance department action—A temporary regulation defines how many and what types of tests must be completed and how they should be disclosed. Types of questions which may be asked also specified. Informed consent required.

**Table 1-4.—State Laws and Regulations Concerning HIV Antibody Testing by Health Insurers (as of April 1988)
(continued)**

Maine:

Legislation—No insurer may request any person to reveal whether the person has obtained a test for the presence of antibodies to the AIDS virus prior to an application for insurance coverage. Prohibits testing without informed consent.

Maryland:

Insurance department action—Guidelines issued specify types of tests to use and restrict questions on the application to those that elicit specific medical information rather than lifestyle or sexual orientation inferences. Informed consent required.

Massachusetts:

Legislation—Prohibits health care providers from testing without informed consent.

Insurance department action—A regulation prohibits requiring or requesting health insurance applicants to take any HIV-related test. Includes a nondiscrimination provision which prohibits underwriting based on factors such as lifestyle or living arrangements. Implementation is currently stayed by court order. A regulation states that no insurer may ask a proposed insured about a prior HIV-related test or the result and are prohibited from considering any such information in determining insurability.

New Jersey:

Insurance department action—A bulletin prohibits testing for group health insurance yet permits it for individual coverage if it is "medically justified". Blood testing may not be requested based on information about the applicant's lifestyle and, when used, must be ELISA-ELISA-Western blot series. Stipulation on type of question permitted referring to AIDS tests. Informed consent required.

New York:

Insurance department action—A regulation prohibits denying health insurance to an individual based on results of a test used to determine HIV antibody status. Insurers may not request an applicant to submit to a test, or ask whether he has taken such a test, or consider the results of any previously administered test. Implementation was prohibited by court order.

Oregon:

Legislation—Insurance organizations must obtain written consent before testing for HIV antibodies.

Insurance department action—Temporary rules adopted

contain the NAIC underwriting guidelines. Three-test protocol required (ELISA-ELISA-Western blot). Policies must cover HIV infection. No general question regarding taking an HIV test is permitted, though the direct question asking if the applicant has ever tested positive for HIV is allowed.

Rhode Island:

Insurance department action—A proposed regulation prohibits testing for group policies, but permits it for individual policies. Also includes the NAIC guidelines.

South Dakota:

Insurance department action—The NAIC guidelines have been adopted; testing is permitted. Informed consent required.

Texas:

Legislation—Prohibits testing for HIV infection with specified exceptions.

Insurance department action—A proposed regulation clarifies the law, allows testing, and contains testing protocol (ELISA-ELISA-Western blot). A proposed regulation prohibits discrimination and contains the NAIC guidelines. Informed consent required.

Washington:

Insurance department action—A regulation permits testing only on a nondiscriminatory basis, and requires a test with high degree of accuracy before an applicant may be declined or rated substandard. Ambiguous or misleading questions on the application are prohibited.

West Virginia:

Legislation—Prohibits insurers from canceling or not renewing policies because of a diagnosis or treatment of AIDS.

Wisconsin:

Legislation—Prohibits insurers from requiring HIV tests or using test results in determining individual health insurance rates unless the tests are deemed medically significant by the State epidemiologist and sufficiently reliable by the Commissioner of Insurance. Testing for group coverage prohibited.

Insurance department action—A regulation accepts the approval of the ELISA/ELISA-Western blot series for HIV testing from the State epidemiologist. Another regulation prohibits discrimination because of sexual orientation. Informed consent required. NAIC guidelines adopted.

Table 1-5.—Health Insurance Legislation Before the 100th Congress (as of April 1988) Concerning Coverage for the Uninsured and Provisions for High-Risk Individuals (Excluding Medicare-Specific Legislation)

Legislation for High Risk Individuals:

S. 24/H.R. 276—Amends the Social Security Act to eliminate, for five years, the requirement that an individual be entitled to disability benefits for at least 24 consecutive months in order to qualify for hospital insurance benefits for those with AIDS.

S. 1634—*Access to Health Insurance for Medically Uninsurable Individuals Act of 1987*—Encourages States to set up pooling mechanisms through a ten million dollar grant program to provide health insurance for medically uninsurable individuals. States will receive funds based on their proportionate share of the national population to be used toward establishing health insurance risk pools. The States themselves would be responsible for financing, design, and subsidization of the pools.

H.R. 406—*National Catastrophic Illness Protection Act of 1987*—Amends the Social Security Act to establish a national catastrophic illness insurance program under which the Federal Government, working in conjunction with State insurance authorities and the private insurance industry, will make adequate health protection available to all Americans at reasonable cost. The program will involve the creation of State-wide plans providing extended health insurance with the Federal Government reinsuring insurers and pools of insurers offering such insurance.

H.R. 1182—*Health Services Act of 1987*—Amends the Social Security Act to establish a public/private program to provide health services to the medically uninsured not eligible for Medicaid. The program will provide benefits to residents of a State where there exists a Statewide Pooling Corporation. A Federal Health Trust Fund will be established to pay direct grants to such corporations.

H.R. 2300—*Catastrophic Illness Expense Protection Amendments of 1987*—Amends the Internal Revenue Code to deny employers an income tax deduction for group health plan expenses unless the plan provides full catastrophic coverage for physician and hospital services provided to a covered employee or family member during any period within the plan year after out-of-pocket expenses for certain medical services exceed \$2,000 (\$3,500 for family coverage) and does not cancel or differentiate in coverage except in cases of failure to pay premiums due.

H.R. 3766—*Comprehensive Health Care Improvement Act of 1987*—A bill to provide for certification and require the offering of qualified health plans, to provide Federal assistance to States to establish a program of assistance for low-income persons to purchase comprehensive health insurance, and a program for coverage of catastrophic health care expenses.

Legislation For Those With No Health Insurance Coverage:

S. 177—*Health Care for the Uninsured Act of 1987*—Permits States to establish health care pools to provide health care services to all uninsured individuals and to share among all hospitals in the State the costs of the uncompensated care. Requires the implementation of the health care pool at the Federal level where a State does not establish such a program or receive a waiver from the Secretary of Health and Human Services. Each uninsured individual seeking coverage through the pool will pay a premium based on the individual's family income.

S. 1139/H.R. 3580—*MedAmerica Act of 1987*—Amends the

Social Security Act to give States the option of extending coverage to:

- individuals whose family income does not exceed an income level established by the State at or below 200 percent of the Federal poverty level;
- those who are unable to obtain health insurance coverage from another source by reason of a preexisting medical condition;
- those who have exhausted some or all of the benefits under their health insurance policy; and
- those whose employer employs no more than 25 individuals and is unable to provide adequate health insurance coverage for such individuals at a reasonable cost.

S. 1265/H.R. 2508—*Minimum Health Benefits for All Workers Act of 1987*—Amends the Public Health Service Act to require each employer to enroll each of its employees and their families in a health benefit plan. Makes State employers which do not so enroll their employees and their families ineligible to receive grants, contracts, loans, or loan guarantees under such Act. Amends Fair Labor Standards Act of 1938 and Employee Retirement Income Security Act of 1974 to require each employer to enroll each of its employees and their families in a health benefit plan. Amends ERISA regarding superseding of State laws relating to contracts or policies of insurance issued to or under a health benefit plan under this Act.

S. 1370—Amends the Internal Revenue Code to increase from 25 to 80 percent the income tax deduction for the health insurance costs of a self-employed individual.

S. 1386—Amends the Internal Revenue Code to increase the income tax deduction for the amount of health insurance costs of a self-employed individuals from 25 to 100 percent. Permits income tax deductions for self-employed individuals in the amount of their contributions to group health plans that are not self-insured and that provide medical benefits to employees.

H.R. 200—*USHealth Program Act*—Amends the Social Security Act to ensure access for all Americans to quality health care, regardless of age or disability, while containing the costs of the health care system.

H.R. 955—*Health Care Savings Act of 1987*—Amends the Internal Revenue Code to permit individuals and employers to contribute to health care savings accounts. Limits the amount which may be contributed to a health care savings account each year to no greater than the combined amount of employee and employer hospital insurance payroll tax paid during that year. The employee and the employer will each receive a 60 percent tax credit for their respective portion of their hospital insurance payroll tax paid.

H.R. 2696—*Universal Health Insurance Act of 1987*—Amends the Social Security Act to make health insurance widely available to all U.S. citizens. Each enrollee shall pay a premium equal to six percent of the sum of the amount of an individual's verified income and the amount of the individual's net assets.

H.R. 3065—(no title)—Amends the Internal Revenue Code provisions relating to the income tax deduction for the health insurance costs of self-employed individuals to increase from 25 to 100 percent the allowable deduction and make the deduction permanent.

H.R. 3766—*Comprehensive Health Care Improvement Act of 1987*—See above.

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- Staff Paper:

- AIDS and Health Insurance: An OTA Survey.*
February 1988. GPO stock #052-003-01093-3; \$2.75.

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- The Impact of AIDS on the Kaiser Permanente Medical Care Program (Northern California Region).* July 1988. GPO stock #052-003-01128-0; \$2.25.

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